Appendix A: Detailed Electronic Database Search Strategies

PubMed Strategy

Terms	Returns
((“Diabetes Mellitus”[mh] OR Diabet*[tiab] OR hyperglycem*[tiab] OR hyperglycaem*[tiab]) AND (“Insulin Infusion Systems”[mh] OR “continuous subcutaneous insulin”[tiab] OR CSII[tiab] OR “insulin pump”[tiab] OR “insulin pumps”[tiab] OR “pump therapy”[tiab] OR “pump treatment”[tiab] OR “artificial pancreas”[tiab] OR (“Monitoring, Ambulatory”[mh] AND (glucose[tiab] OR insulin[tiab] OR glycem*[tiab] OR glycaem*[tiab])) OR “CGM”[tiab] OR (“continuous glucose”[tiab] AND (monitor*[tiab] OR sensing[tiab] OR sensor*[tiab])))) NOT (animal[mh] NOT human [mh])	4341

EMBASE Strategy

(('diabetes mellitus'/exp OR diabet*:ti,ab OR hyperglycem*:ti,ab OR hyperglycaem*:ti,ab) AND ('insulin pump'/de OR “continuous subcutaneous insulin”:ti,ab OR CSII:ti,ab OR “insulin pump”:ti,ab OR “insulin pumps”:ti,ab OR “pump therapy”:ti,ab OR “pump treatment”:ti,ab OR “artificial pancreas”:ti,ab OR ('blood glucose monitoring'/exp AND (continu*:ti,ab OR real-time:ti,ab)) OR CGM:ti,ab OR (“continuous glucose”:ti,ab AND (monitor*:ti,ab OR sensing:ti,ab OR sensor*:ti,ab)))) NOT ([animals]/lim NOT [humans]/lim)ustekinumab:ab,ti OR 'budesonide'/exp OR 'budesonide' OR 'methylprednisolone'/exp OR 'methylprednisolone' OR 'prednisolone'/exp OR 'prednisolone' OR 'prednisone'/exp OR 'prednisone' OR '6-methylprednisolone':ab,ti OR budesonide:ab,ti OR corticosteroid*:ab,ti OR glucocorticosteroid*:ab,ti OR prednisolone:ab,ti OR prednisone:ab,ti) NOT ([animals]/lim NOT [humans]/lim) NOT (letter:it OR comment:it OR editorial:it) AND ('article'/it OR 'review'/it OR 'article in press'/it)	4931

The Cochrane Central Register of Controlled Trials (CENTRAL)

((Diabet*:ti,ab,kw OR hyperglycem*:ti,ab,kw OR hyperglycaem*:ti,ab,kw) AND (“continuous subcutaneous insulin”:ti,ab,kw OR CSII:ti,ab,kw OR “insulin pump”:ti,ab,kw OR “insulin pumps”:ti,ab,kw OR “pump therapy”:ti,ab,kw OR “pump treatment”:ti,ab,kw OR “artificial pancreas”:ti,ab,kw OR “CGM”:ti,ab,kw OR (“continuous glucose”:ti,ab,kw AND (monitor*:ti,ab,kw OR sensing:ti,ab,kw OR sensor*:ti,ab,kw))))	192 from Clinical Trials

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
Rethnam U, Yesupalan RS, Sinha A.

Submit Form and go to or Skip to Next

1. Does this citation **POTENTIALLY** apply to our key questions?

Yes No Clear Response

Submit Form and go to or Skip to Next

Refid 8: Percival, M. W., Bevier, W. C., Wang, Y., Dassau, E., Zisser, H. C., Jovanovic, L., and Doyle, F. J. 3rd. Modeling the effects of subcutaneous insulin administration and carbohydrate consumption o glucose. J Diabetes Sci Technol. 2010. 4

BACKGROUND: Estimation of the magnitude and duration of effects of carbohydrate (CHO) and subcutaneously administered insulin on blood glucose (BG) is required for improved BG regulation in people with type 1 diabetes mellitus (T1DM). The goal of this study was to quantify these effects in people with T1DM using a novel protocol.

METHODS: The protocol duration was 8 hours: a 1-3 U subcutaneous (SC) insulin bolus was administered and a 25-g CHO meal was consumed, with these inputs separated by 3-5 hours. The DexCom SEVEN(R) PLUS continuous glucose monitor was used to obtain SC glucose measurements every 5 minutes and YSI 2300 Stat Plus was used to obtain intravenous glucose measurements every 15 minutes.

RESULTS: The protocol was tested on 11 subjects at Sansum Diabetes Research Institute. The intersubject parameter coefficient of variation for the best identification method was 170%. The mean percentages of output variation explained by the bolus insulin and meal models were 68 and 69%, respectively, with root mean square error of 14 and 10 mg/dl, respectively. Relationships between the model parameters and clinical parameters were observed.

CONCLUSION: Separation of insulin boluses and meals in time allowed unique identification of model parameters. The wide intersubject variation in parameters supports the notion that glucose-insulin models and thus insulin delivery algorithms for people with T1DM should be personalized. This experimental protocol could be used to refine estimates of the correction factor and the insulin-to-carbohydrate ratio used by people with T1DM.

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Insulin Pump Therapy With and Without Continuous Glucose Monitoring for Diabetes
Abstract Review Form

Exclude article because (check at least one response)

- ☐ No original data
- ☐ No formal diagnosis of diabetes (we are excluding MODY and gestational diabetes)
- ☐ Does not evaluate continuous subcutaneous insulin infusion therapy or real-time continuous glucose monitoring (we are excluding implantable insulin pumps)
- ☐ Does not compare to placebo or usual care (multiple daily injections is defined as at least 3 injections of basal and rapid-acting insulin per day; self-monitoring of blood glucose defined as at least 3 fingersticks/day)
- ☐ Usage time of device less than 24 hours
- ☐ Not in an outpatient setting
- ☐ Case series of case reports or cross-sectional
- ☐ No human subjects
- ☐ Does not apply to a key question
- ☐ Other (specify):

2. *Unclear*

- ☐ Unclear-pull article for review

3. *Include* article for review

- ☐ Include

4. Handsearch

- ☐ Exclude from review, but pull for handsearching (e.g. systematic review that applies to key question and published since 2005)

5. Comments **(limit to 250 characters)**

Submit Form and go to This Form - Next Reference or Skip to Next

View Audit Log

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
Rethnam U, Yesupalan RS, Sinha A.

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Insulin Pump Therapy With and Without Continuous Glucose Monitoring for Diabetes
Article Review Form

1. *Exclude* article because (check at least one response)

- ☐ No original data
- ☐ No formal diagnosis of diabetes (we are excluding MODY and gestational diabetes)
- ☐ Does not evaluate continuous subcutaneous insulin infusion therapy or real-time continuous glucose monitoring (we are excluding implantable insulin pumps, artificial pancreas, and closed-loop systems)
- ☐ Does not compare to placebo or usual care (multiple daily injections is defind as at least 3 fingersticks/day)
- ☐ No concurrent comparison group
- ☐ Does not have an outcome of interest (see list below)
- ☐ Usage time of device less than 24 hours
- ☐ Not in an outpatient setting
- ☐ Case series or case reports or cross-sectional or meeting abstract
- ☐ No human subjects
- ☐ Does not apply to a key question
- ☐ Other (specify):
- ☐ Regular insulin used in pump
- ☐ Observational study that does not evaluate a microvascular, macrovascular, maternal, or fetal outcome

2. *Include* article for review (indicate the following):

- ☐ RCT
- ☐ Observational
- ☐ Continuous subcutaneous insulin infusion or insulin pump
- ☐ Real-time continuous glucose monitor

3. *Handsearch*

- ☐ Exclude from review, but pull for handsearching (e.g., systematic review that applies to the key question and published since 2005)

Outcomes of interest

Process Measures	Intermediate Outcomes	Clinical Outcomes	Maternal and Fetal Outcomes
Ratio of basal to bolus insulin Frequency of adjusting insulin therapy Adherence to insulin therapy/sensor use	Primary HbA1C Secondary Quality of life Hyperglycemia Weight Gain Hypoglycemia frequency	Microvascular Retinopathy Nephropathy Neuropathy Macrovascular Coronoary heart disease Cerebrovascular disease Peripheral arterial disease Severe hypoglycemia	Maternal pregnancy outcomes Antenatal hospital stay (% requiring admission, length of stay) C-section rates Fetal outcomes Gestational age Birth weight Frequency of neonatal hypoglycemia Birth trauma Major and minor anomalies Neonatal intensive care unit admission

4. Comments **(Limit 250 characters)**

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Rethnam U, Yesupalan RS, Sinha A.

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Comparative Effectiveness of Insulin Pump Therapy
With or Without Continuous Glucose Monitoring in Diabetes
Study Design Form

Additional Screening Questions

1. Is this study an observational study that reports on microvascular, macrovascular, maternal, or fetal outcomes?

- ☐ No, not an observational one **(CONTINUE)**
- ☐ Yes, this is an observational study that reports on microvascular, macrovascular, maternal, or fetal outcomes **(CONTINUE)**
- ☐ No, this is an observational study DOES NOT REPORT on microvascular, macrovascular, maternal, or fetal outcomes **(STOP! E-MAIL LISA TO EXCLUDE THIS STUDY)**

2. Is regular insulin being used in the insulin pumps?

- ☐ Yes, regular insulin is being used in the insulin pumps **(STOP! EMAIL LISA TO EXCLUDE THIS STUDY)**
- ☐ No, regular insulin is NOT being used in the insulin pumps **(CONTINUE)**

Study Design Form

1. Where did the study occur? **(Check all that apply)**

- ☐ United States
- ☐ Canada
- ☐ Worldwide
- ☐ Other (specify):
- ☐ Not reported

2. When was the study enrollment period? **(enter the 4-digit year for start and/or end, or indicate not reported)**

- ☐ Start year:
- ☐ End year:
- ☐ Not reported

3. What was the total intended follow up duration or maximum possible follow up?

Select an Answer

4. What was the total number of patients screened?

Select an Answer

5. What was the total number at enrollment or cohort inception?

Select an Answer

6. What was the source of the population from which subjects were enrolled in the study? **(Check all that apply)**

- ☐ Diabetes referral clinic
- ☐ General medicine clinic
- ☐ Ob/Gyn Clinic
- ☐ Other (specify):
- ☐ Not reported

7. What study design was used? **(Check all that apply)**

Select an Answer

8. Was there a run-in period? **(Choose only one response)**

Select an Answer

9. Select trial type **(Check only one response)**

- Parallel arms
- Factorial design
- Crossover design
- Other (specify):
- Not applicable

10. Please select the included patient population

Diabetes status **(choose only one response)**	Age **(Choose all that apply)**	Pregnancy status **(choose only one response)**
Type 1 diabetes	Very young children	Pregnant women exclusively
Type 2 diabetes	Adolescents	Pregnant women included
Both	Adults	Pregnant women excluded
Other (specify):	Elderly	Not reported
Clear Response	Age Range	Clear Response

11. Please specify the exclusion criteria. Any inclusion critera should be entered as exclusion criteria **(e.g., if the study only included females, then the exclusion criteria would be males).**

- HbA1c >
- HbA1c <
- Male
- Female
- Treated with insulin:
- Not currently receiving intensive insulin therapy (either insulin pump or multiple daily injections)
- Use of insulin pump therapy within:
- Use of continuous glucose monitoring within:
- Use of oral hypoglycemic within:
- Not using adequate contraception
- Other (specify):
- Other (specify):
- Other (specify):
- Other (specify):
- Other (specify):
- Other (specify):

12. Was there industry support (funding or drug given) or government support for the study? **(Check all that apply)**

- Yes, industry support
- Yes, government support
- Yes, other support
- No
- Not reported

13. Does this study report on quality of life?

- Yes
- No

Clear Response

Comments:

Comments:

Comments:

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Comparative Effectiveness of Insulin Pump Therapy
With or Without Continuous Glucose Monitoring in Diabetes
Population Characteristics Form

	Group 1	Group 2	Group 3	Group 4
Number enrolled				
Age Age NR Clear Response	Mean: Median: Age range:	Mean: Median: Age range:	Mean: Median: Age range:	Mean: Median: Age range:
Gender Gender NR Clear Response	Male, n: Male, %:	Male, n: Male, %:	Male, n: Male, %:	Male, n: Male, %:
Race Race NR Clear Response	African American, n: African American, %: Asian or Asian American, n: Asian or Asian American, %: Caucasian, n: Caucasian, %: Hispanic, n: Hispanic, %: Other race, n: Other race, %:	African American, n: African American, %: Asian or Asian American, n: Asian or Asian American, %: Caucasian, n: Caucasian, %: Hispanic, n: Hispanic, %: Other race, n: Other race, %:	African American, n: African American, %: Asian or Asian American, n: Asian or Asian American, %: Caucasian, n: Caucasian, %: Hispanic, n: Hispanic, %: Other race, n: Other race, %:	African American, n: African American, %: Asian or Asian American, Asian or Asian American, Caucasian, n: Caucasian, %: Hispanic, n: Hispanic, %: Other race, n: Other race, %:
HbA1c HbA1c NR Clear Response	Mean HbA1c: Median HbA1c: HbA1c range:	Mean HbA1c: Median HbA1c: HbA1c range:	Mean HbA1c: Median HbA1c: HbA1c range:	Mean HbA1c: Median HbA1c: HbA1c range:
BMI/Weight BMI/Weight NR Clear Response	Mean BMI (kg/m²): Median BMI (kg/m²): Mean weight (kg): Median weight (kg):	Mean BMI (kg/m²): Median BMI (kg/m²): Mean weight (kg): Median weight (kg):	Mean BMI (kg/m²): Median BMI (kg/m²): Mean weight (kg): Median weight (kg):	Mean BMI (kg/m²): Median BMI (kg/m²): Mean weight (kg): Median weight (kg):
Duration of Diabetes Duration of diabetes NR Clear Response	Mean (years): Median (years):	Mean (years): Median (years):	Mean (years): Median (years):	Mean (years): Median (years):
Insulin delivery method (Answer question for studies evaluating blood glucose monitoring) Insulin delivery method NR Clear Response	CSII, n: CSII, %: Multiple daily injections, n: Multiple daily injections, %:	CSII, n: CSII, %: Multiple daily injections, n: Multiple daily injections, %:	CSII, n: CSII, %: Multiple daily injections, n: Multiple daily injections, %:	CSII, n: CSII, %: Multiple daily injections, n Multiple daily injections, %
Number of withdrawals Number of withdrawals NR Clear Response	N:	N:	N:	N:

Comments:

Comments:

Comments:

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Comparative Effectiveness of Insulin Pump Therapy
With or Without Continuous Glucose Monitoring in Diabetes
Intervention Characteristics Form

1. Identify study group: **(For studies evaluating insulin delivery methods, please identify group 1 as multiple daily injection. For studies evaluating blood glucose monitoring, please identify group 1 as self-monitoring of blood glucose.)**

Select an Answer

(Answer Q2-5 for insulin delivery methods)

2. What type of insulin delivery method was used? **(Select all that apply)**	3. What type of insulin was used? **(Select all that apply)**	4. Was there any training before initiating the insulin pump? **(Select one response)**	5. What was the schedule for multiple daily injections?
Multiple daily injections Insulin pump, model unspecified Abbott Aviator Abbott Freestyle Aviator Animas Model IR 1000 Animas Model IR 1200 Animas Model IR 1250 Cane Microjet Quark model U-100 Cardiac Pacemakers Betatron IV insulin infusion system Deltec/Smiths Medical Cozmo Insulin Infusion Pump Disetronic/Roche H-TRON V 100 Disetronic/Roche DAHEDI Disetronic/Roche D-TRON Disetronic/Roche ACCU-Check Spirit Insulet iXL Diabetes management system Insulet iXL-11 DMS Mendigo Solo insulin patch pump Mendigo Solo Micropump insulin delivery system Medtronic Minimed Model 506 Medtronic Minimed Model MMT-507 Medtronic Minimed Model 505 Medtronic Minimed Model 507c Medtronic Minimed Model 508 Medtronic Minimed Paradigm model 512 Medtronic Minimed REAL-time system Medtronic Minimed Paradigm 722 NiliMedix ADI Nipro Glucopro infusion pump Nipro Amigo Pharma-Plast Sooil DANA Diabecare Sooil DANA Diabecare II Sooil DANA Diabecare IIS Other type of insulin pump (Specify):	Insulin aspart Insulin detemir Insulin glargine Insulin glulisine Insulin lispro NPH insulin Regular insulin Other type of insulin (Specify): Not reported	Yes No Not reported	3 times/day 4 + times/day Other (specify): Not reported

(Answer Q6-10 for blood glucose monitoring techniques.)

6. What type of blood glucose monitoring technique was used?	7. How often was the monitor used?	8. What were the alarms for hypoglcycemia?	9. What were the alarms for hyperglycemia?	10. What was the frequency and schedule of blood glucose monitoring?
Self-monitoring blood glucose Real-time continuous glucose monitor, model unspecified Abbott Freestyle Navigator Dexcom STS		Select an Answer	Select an Answer	Select an Answer

- [ ] Medtronic Minimed Guardian Telemetered CGM
- [ ] Minimed Guardian Real-Time CGM
- [ ] Minimed Medtronic Paradigm RT
- [ ] Other real-time continuous glucose monitor (specify):

(Answer for all interventions.)

11. What was the total duration of therapy?

Select an Answer

12. Where there guidelines for provider insulin dose titration?

- ○ Yes
- ○ No
- ○ Not reported

Clear Response

13. Please indicate the target glycemic

- [ ] HbA1c (%):
- [ ] Fasting glucose (mg/dL):
- [ ] Fasting glucose (mmol/L):
- [ ] Preprandial glucose (mg/dL):
- [ ] Preprandial glucose (mmol/L):
- [ ] 2-hr postprandial glucose (mg/dL):
- [ ] 2-hr postprandial glucose (mmol/L):
- [ ] Other glycemic target (mg/dL):
- [ ] Other glycemic target (mmol/L):
- [ ] Not reported

14. Were there guidelines for between visit titration?

- ○ Yes
- ○ No
- ○ Not reported

Clear Response

Submit Form and go to or Skip to Next

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Rethnam U, Yesupalan RS, Sinha A.

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Comparative Effectiveness of Insulin Pump Therapy With or Without Continuous Monitoring in Diabetes
Outcomes Form

Please complete this form for RCTs and cohort studies. Submit one form per relevant outcome.

Please select one outcome	**Please define outcome**	**If study reports results stratified only, please indicated which population is being reported here.**
Process measures Ratio of basal to bolus insulin Frequency of adjusting insulin therapy Adherance to insulin therapy/sensor use Frequency of physician or allied health visit Clear Response	Proportion of basal insulin Number of daily boluses Average use/week Other definition: Clear Response	Type 1 diabetes Type 2 diabetes Age range: Clear Response
Intermediate outcomes HbA1c Hyperglycemia Weight gain Hypoglycemia frequency Clear Response	% Fasting glucose (mg/dL): Fasting glucose (mmol/L): Postprandial glucose (mg/dL): Postprandial glucose (mmol/L): kg lb Mild hypoglycemia: Moderate hypoglycemia: Nocturnal hypoglycemia: Daytime hypoglycemia: Clear Response	Type 1 Diabetes Type 2 Diabetes Age range: Clear Response
Clinical Outcomes Retinopathy Nephropathy Neuropathy Coronary heart disease Cerebrovascular disease Peripheral arterial disease Severe hypoglycemia Clear Response	Specify: Not further specified Clear Response	Type 1 diabetes Type 2 diabetes Age Range Clear Response
Fetal outcomes Gestational age Birth weight Frequency of neonatal hypoglycemia Birth trauma Major anomalies Minor anomalies Minor anomalies NICU admission NICU admission Clear Response	Weeks kg Specify: Clear Response	Type 1 diabetes Type 2 diabetes Age range: Clear Response
Maternal outcomes Cesarean delivery Clear Response	Elective Repeat Specify:	Type 1 diabetes Type 2 diabetes Age range: Clear Response

	○ Not further specified Clear Response	

When was this outcome assessed? **(Only report the last timepoint. For pregnancy studies, record events for each trimester, however do not report results for the post natal period.)**

- ○ Weeks
- ○ Months
- ○ Years
- ○ First trimester
- ○ Second trimester
- ○ Third trimester
- ○ Not reported

Clear Response

Table 1. Incidence of outcome

Intervention	N for analysis	Outcome measure	Denominator	P-value	Reference group
Group1		☐ # of patients with one or more events ☐ % of patients with one or more events ☐ # of events	Select an Answer		Select an Answer
Intervention Group2	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events ☐ % of patients with one or more events ☐ # of events	Select an Answer		Select an Answer
Intervention Group3	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events ☐ % of patients with one or more events ☐ # of events	Select an Answer		Select an Answer
Intervention Group4	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events ☐ % of patients with one or more events ☐ # of events	Select an Answer		Select an Answer
Intervention Group5	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events ☐ % of patients with one or more events ☐ # of events	Select an Answer		Select an Answer
Intervention Group6	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events ☐ % of patients with one or more events ☐ # of events	Select an Answer		Select an Answer
Intervention Group7	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events ☐ % of patients with one or more events ☐ # of events	Select an Answer		Select an Answer
Intervention Group8	N for analysis	Outcome measure	Denominator	P-value	Reference group
		☐ # of patients with one or more events ☐ % of patients with one or more events ☐ # of events	Select an Answer		Select an Answer

Table 2. Measure of Association

Intervention	N for analysis	Point estimate (Select one response)	Measure of variability (Select one response)	95%CI	P-value	Reference group

		Select an Answer	Select an Answer			
Intervention Group1				☐ LL ☐ UL		Select an Answer
Intervention Group2				☐ LL ☐ UL		Select an Answer
Intervention Group3				☐ LL ☐ UL		Select an Answer
Intervention Group4				☐ LL ☐ UL		Select an Answer
Intervention Group5				☐ LL ☐ UL		Select an Answer
Intervention Group6				☐ LL ☐ UL		Select an Answer
Intervention Group7				☐ LL ☐ UL		Select an Answer
Intervention Group8				☐ LL ☐ UL		Select an Answer

If a multivariable analysis, what other variables were adjusted for in the model? **(Select all that apply)**

- ☐ Matching factors
- ☐ Age
- ☐ Sex
- ☐ Race/ethnicity
- ☐ Duration of disease
- ☐ Other (specify):
- ☐ Other (specify):
- ☐ Other (specify):
- ☐ Results not adjusted

Table 3. Mean difference from other group

Intervention	**N for analysis**	**Point estimate (Select one response)**	**Measure of variability (Select one response)**	**CI or IQR (Select one response)**	**P-value**	**Reference group**
		Select an Answer	Select an Answer	Select an Answer		
Intervention Group1				☐ LL ☐ UL		Select an Answer
Intervention Group2				☐ LL ☐ UL		Select an Answer
Intervention Group3				☐ LL ☐ UL		Select an Answer
Intervention Group4				☐ LL ☐ UL		Select an Answer

Intervention Group5				☐ LL ☐ UL		Select an Answer
Intervention Group6				☐ LL ☐ UL		Select an Answer
Intervention Group7				☐ LL ☐ UL		Select an Answer
Intervention Group8				☐ LL ☐ UL		Select an Answer

Table 4. Mean difference from baseline.

Intervention	N for analysis	Point estimate (Select one response) Select an Answer	Measure of variability (Select one response) Select an Answer	CI or IQR (Select one response) Select an Answer	P-value
Intervention Group1				☐ LL ☐ UL	
Intervention Group2				☐ LL ☐ UL	
Intervention Group3				☐ LL ☐ UL	
Intervention Group4				☐ LL ☐ UL	
Intervention Group5				☐ LL ☐ UL	
Intervention Group6				☐ LL ☐ UL	
Intervention Group7				☐ LL ☐ UL	
Intervention Group8				☐ LL ☐ UL	

Table 5. Baseline measures.

Intervention	N for analysis	Point estimate (Select one response) Select an Answer	Measure of variability (Select one response) Select an Answer	CI or IQR (Select one response) Select an Answer
Intervention Group1				☐ LL ☐ UL
Intervention Group2				☐ LL ☐ UL

Intervention Group3				☐ LL ☐ UL
Intervention Group4				☐ LL ☐ UL
Intervention Group5				☐ LL ☐ UL
Intervention Group6				☐ LL ☐ UL
Intervention Group7				☐ LL ☐ UL
Intervention Group8				☐ LL ☐ UL

Table 6. Final measures

Intervention	**N for analysis**	**Point estimate (Select one response)** Select an Answer	**Measure of variability (Select one response)** Select an Answer	**CI or IQR (Select one response)** Select an Answer	**P-value**	**Reference group**
Intervention Group1				☐ LL ☐ UL		Select an Answer
Intervention Group2				☐ LL ☐ UL		Select an Answer
Intervention Group3				☐ LL UL		Select an Answer
Intervention Group4				LL UL		Select an Answer
Intervention Group5				LL UL		Select an Answer
Intervention Group6				LL UL		Select an Answer
Intervention Group7				LL UL		Select an Answer
Intervention Group8				LL UL		Select an Answer

Comments **(Limit 250 characters)**

Comments **(Limit 250 characters)**

Comments **(Limit 250 characters)**

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Insulin Pump Therapy With and Without Continuous Glucose Monitoring for Diabetes

Quality form for RCTs

Sequence Generation

1. Was the allocation sequence adequately generated?

Select an Answer

*Criteria for a judgment of "*YES*" (i.e., low risk of bias)*

- *The investigators describe a random component in the sequence generation process such as:*
  - *Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization. Minimization may be implemented without a random element, and this is considered to be equivalent to being random.*

*Criteria for a judgment of "*NO*" (i.e., high risk of bias)*

- *The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:*
  - *Sequence generated by odd or even date of birth;*
  - *Sequence generated by some rule based on date (or day) of admission;*
  - *Sequence generated by some rule based on hospital or clinic record number.*
- *Other non-random approached happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgment or some method of non-random categorization of participants, for example:*
  - *Allocation by judgment of the clinician;*
  - *Allocation by preference of the participant;*
  - *Allocation based on the results of a laboratory test or a series of tests.*

*Criteria for a judgment of "*UNCLEAR*" (i.e., uncertain risk of bias)*

- *Insufficient information about the sequence generation process to permit judgement of "YES" or "NO."*

Allocation Concealment

2. Was allocation adequately concealed?

Select an Answer

*Criteria for a judgment of "*YES*" (i.e. low risk of bias)*

- *Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:*
  - *Central allocation (including telephone, web-based, and pharmacy-controlled, randomization);*
  - *Sequentially numbered drug containers of identical appearance;*
  - *Sequentially numbered, opaque, sealed envelopes.*

*Criteria for a judgment of "*NO*" (i.e. high risk of bias)*

- *Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:*
  - *Using an open random allocation schedule (e.g. a list of random numbers);*
  - *Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered);*
  - *Alternation or rotation;*

- *Date of birth;*
- *Case record number;*
- *Any other explicitly unconcealed procedure*

*Criteria for the judgment of "*UNCLEAR*" (i.e. uncertain risk of bias)*

- *Insufficient information about the sequence generation process to permit judgment of "YES" or "NO".*
  - *This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgment – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.*

Blinding of Participants, Personnel, and Outcome Assessors

3. Was knowledge of the allocated interventions adequately prevented during the study?

Select an Answer

*Criteria for a judgment of "*YES*" (i.e. low risk of bias)*

- *Any one of the following:*
  - *No blinding, but the review authors judge that the outcome and the outcome*
  - *Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken;*
  - *Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the nonblinding of others unlikely to introduce bias.*

*Criteria for a judgment of "*NO*" (i.e. high risk of bias)*

- *Any one of the following:*
  - *No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding;*
  - *Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken;*
  - *Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.*

*Criteria for the judgment of "*UNCLEAR*" (i.e. uncertain risk of bias)*

- *Any one of the following:*
  - *Insufficient information to permit judgment of 'Yes' or 'No';*
  - *The study did not address this outcome.*

Incomplete Outcome Data

4. Were incomplete outcome data adequately addressed?

Select an Answer

*Criteria for a judgment of "*YES*" (i.e. low risk of bias)*

- *Any one of the following:*
  - *No missing outcome data;*
  - *Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);*
  - *Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;*
  - *For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;*
  - *For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;*
  - *Missing data have been imputed using appropriate methods.*

*Criteria for a judgment of "*NO*" (i.e. high risk of bias)*

- *Any one of the following:*
  - *Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;*
  - *For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;*
  - *For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among*

missing outcomes enough to induce clinically relevant bias in observed effect size;
- *'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization;*
- *Potentially inappropriate application of simple imputation*

*Criteria for the judgment of "*UNCLEAR*" (i.e. uncertain risk of bias)*

- *Any one of the following:*
  - *Insufficient reporting of attrition/exclusions to permit judgment of 'Yes' or 'No' (e.g. number randomized not stated, no reasons for missing data provided);*
  - *The study did not address this outcome.*

Pharmaceutical Support

5. Did this study receive support (research funds, medications provided, writing services, author or staff was employee) from a company having a financial interest in any of the medications studied?

Select an Answer

6. If "Yes," did the company have any involvement in the design, conduct, or reporting of the study?
For "NO," the authors are not employees of the company and the authors had complete access to the data, and the company was not involved in the design, conduct, analysis, or reporting of the study.

Select an Answer

Overall Quality of Study

7. Please rate the overall quality of the study:

Select an Answer

*Criteria for a judgment of "*GOOD*" (i.e. low risk of bias)*

- *These studies have the least bias and results are considered valid*
- *A study that adheres mostly to the commonly held concepts of high quality including the following:*
  - *A formal randomized controlled study;*
  - *Clear description of the population, setting, interventions, and comparison groups;*
  - *Appropriate measurements of outcomes;*
  - *Appropriate statistical and analytic methods and reporting;*
  - *No reporting errors;*
  - *Low dropout rate; and*
  - *Clear reporting of dropouts*

*Criteria for a judgment of "*FAIR*"*

- *These studies are susceptible to some bias, but it is not sufficient to invalidate the results.*
- *Do not meet all the criteria required for a rating of good qualities because they have some deficiencies, but no flaw is likely to cause major bias.*
- *The study may be missing information, making it difficult to assess limitations and potential problems*

*Criteria for a judgment of "*POOR*" (i.e. high risk of bias)*

- *These studies have significant flaws that imply biases of various types that may invalidate the results.*
- *Have serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.*

8. Were >20% of the study participants lost to followup at any of the following time points?

Select an Answer

9. Please add comments below.

Submit Form and go to or Skip to Next

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
Rethnam U, Yesupalan RS, Sinha A.

Submit Form and go to or Skip to Next

Insulin Pump Therapy With and Without Continuous Glucose Monitoring for Diabetes
Quality Form for Observational Trials

1. Did the study describe the setting or population from which the study sample was drawn?

   - Yes, complete description including an appropriate sampling scheme (consecutive, random)
   - Yes, but without description of sampling scheme or used a scheme that could bias results (convenience)
   - No or insufficient to replicate

2. Were the inclusion and exclusion criteria for subjects described?

   - Yes
   - No

3. Is there description of key characteristics of the enrolled subjects that could affect outcomes?

   - Yes- with detailed descriptions of covarietes expected to affect outcomes (e.g. age, duration of diabetes, other therapies)
   - Some description of covariates (e.g. age, sex)
   - No

4. Were the patients in each of the intervention groups or the cases and controls recruited from the same population?

   - Yes
   - No
   - Unclear

5. Are the results presented adjusted or stratified for differences in groups or stated that the groups were comparable at baseline?

   - Yes
   - No
   - Not applicable

6. Does the study describe the number of participants who were lost to follow-up after the start of the period of observation?

   - Yes
   - No
   - Not applicable (e.g. cross-sectional study)
   - Unclear

7. What percentage of patients was lost to follow-up?

   - <10% in any group
   - 10-20% in any group
   - >20%
   - Not reported

8. Please rate the overall quality of the study.

   - Good (low risk of bias). These studies have the least bias and results are considered valid. A study that adheres mostly to the commonly held concepts of high quality including the following: a formal randomized controlled study; clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; low dropout rate; and clear reporting of dropouts.

○ Fair. These studies are susceptible to some bias, but it is not sufficient to invalidate the results. They do not meet all the criteria required for a rating of good quality because they have some deficiencies, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems.

○ Poor (high risk of bias). These studies have significant flaws that imply biases of various types that may invalidate the results. They have serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

9. Comments **(limit 250 characters)**

10. Comments **(limit 250 characters)**

11. Comments **(limit 250 characters)**

Submit Form and go to or Skip to Next

Appendix C: Exclusion Report

Abaci, A., Atas, A., Unuvar, T., Demir, K., Bober, E., and Buyukgebiz, A. A comparison of multiple daily insulin therapy with continuous subcutaneous insulin infusion therapy in adolescents with type 1 diabetes mellitus: a single-center experience from Turkey. J Pediatr Endocrinol Metab 2009; 22(6):539-45.
No concurrent comparison group

Adamson, U. and Lins, P. E. [Insulin pump--25 years old and with a future. It counteracts development of late diabetic complications]. Lakartidningen 2002; 99(51-52):5168-70.
Other reason

Ahmann, A., Buse, J. B., Berganstal, R. M., and Tanenberg, R. HbA1c and sensor use in adults during a 1-year randomised controlled trial comparing sensor-augmented pump therapy and multiple daily injection therapy. Diabetologia 2010; 53:S401.
Case series or cross-sectional

Akhmedova, N. D., Akbarov, Z. S., and Turakulov IaKh [Effect of long-term subcutaneous infusion of insulin using an attached drug dosing device on indices of hemocoagulation in type I diabetes mellitus]. Probl Endokrinol (Mosk) 88; 34(5):11-Jul.
No outcome of interest

Albin, F., Dazet, D., and Haardt, M. J. [Placing of an insulin pump. Subcutaneous route]. Soins 85; (459-460):III-IV.
No original data

Albisser, A. M. and Zinman, B. Insulin dependent diabetes and the artificial pancreas. Med Prog Technol 82; 9(03-Feb):113-8.
No original data

Alemzadeh, R., Ellis, J. N., Holzum, M. K., Parton, E. A., and Wyatt, D. T. Beneficial effects of continuous subcutaneous insulin infusion and flexible multiple daily insulin regimen using insulin glargine in type 1 diabetes. Pediatrics 2004; 114(1):e91-5.
Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

Alemzadeh, R., Loppnow, C., Parton, E., and Kirby, M. Glucose sensor evaluation of glycemic instability in pediatric type 1 diabetes mellitus. Diabetes Technol Ther 2003; 5(2):167-73.
Does not evaluate CSII or rt-CGM

Alemzadeh, R., Palma-Sisto, P., Parton, E. A., and Holzum, M. K. Continuous subcutaneous insulin infusion and multiple dose of insulin regimen display similar patterns of blood glucose excursions in pediatric type 1 diabetes. Diabetes Technol Ther 2005; 7(4):587-96.
Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

Allen, N. A. Continuous glucose monitoring improved glucose control in adults but not in young adults or children with type 1 diabetes. Evid Based Nurs 2009; 12(2):44.
No comparison with placebo or usual care

Allen, N. A., Fain, J. A., Braun, B., and Chipkin, S. R. Continuous glucose monitoring counseling improves physical activity behaviors of individuals with type 2 diabetes: A randomized clinical trial. Diabetes Res Clin Pract 2008; 80(3):371-9.
Does not evaluate CSII or rt-CGM

Allouche, C., Barjot, P., Six, T., Muller, G., and Levy, G. [Insulin dependent diabetes and pregnancy: evaluation of the insulin pump]. J Gynecol Obstet Biol Reprod (Paris) 94; 23(6):706-11.
No outcome of interest

Alvarez, M. G. and Donlo, I. C. Cost-utility of insulin pumps in the treatment of type 1 diabetes in Spain. When most expensive is best (or not): Coste-utilidad de las bombas de insulina en el tratamiento de la diabetes tipo 1 en Espana. Cuando lo mas caro puede ser lo mejor (o no). Endocrinol. Nutr. 2007; 54(2):73-75.
No original data

Amemiya, S., Kato, K., and Asayama, K. The improved response in endogenous insulin due to continuous subcutaneous infusion of insulin therapy in juvenile diabetes. Tohoku J Exp Med 83; 141 Suppl:713-7.
No comparison with placebo or usual care

Anderson, D. G. Multiple daily injections in young patients using the ezy-BICC bolus insulin calculation card, compared to mixed insulin and CSII. Pediatr Diabetes 2009; 10(5):304-9.
Does not apply to a key question

Anon. [Continuous blood glucose values. Monitoring around the clock]. MMW Fortschr Med 2002; 144(50):68-9.
No original data

Anon. [Report from experience: diabetics in the hospital]. Pflege Z 99; 52(10):693.
No original data

Anon. Acute mishaps during insulin pump treatment. Lancet 85; 1(8434):911-2.
No original data

Anon. Blood glucose control and the evolution of diabetic retinopathy and albuminuria. A preliminary multicenter trial. The Kroc Collaborative Study Group. N Engl J Med 84; 311(6):365-72.
No comparison with placebo or usual care

Anon. Collaborative studies of the effects of continuous subcutaneous insulin infusion in insulin-dependent diabetes mellitus. Conclusions. The Kroc Collaborative Study Group. Diabetes 85; 34 Suppl 3:87-9.
No original data

Anon. Diabetic retinopathy after two years of intensified insulin treatment. Follow-up of the Kroc Collaborative Study. The Kroc Collaborative Study Group. JAMA 88; 260(1):37-41.
No comparison with placebo or usual care

Anon. EASD Study Group Artificial Insulin Delivery Systems Pancreas and Islet Transplantation (AIDSPIT). Report of the 13th Workshop of the EASD Study Group AIDSPIT. Diabetologia 94; 37(8):suppl 33-7.
No original data

Anon. Effect of 6 months of strict metabolic control on eye and kidney function in insulin-dependent diabetics with background retinopathy. Steno study group. Lancet 82; 1(8264):121-4.
No comparison with placebo or usual care

Anon. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes (The New England Journal of Medicine (2010) 363, (311-20)). New Engl. J. Med. 2010; 363(11):1092.
Does not evaluate CSII or rt-CGM

Anon. Implementation of treatment protocols in the Diabetes Control and Complications Trial. Diabetes Care 95; 18(3):361-76.
Regular insulin was used in the pump

Anon. Influence of intensive diabetes treatment on body weight and composition of adults with type 1 diabetes in the Diabetes Control and Complications Trial. Diabetes Care 2001; 24(10):1711-21.
Does not apply to a key question

Anon. Insulin pump therapy and serum amyloid A. Lancet 84; 1(8381):853-4.
No original data

Anon. Long-term therapy with insulin pumps assessed. PHARM. PRACT. NEWS 85; 12(11):12.
No concurrent comparison group

Anon. Progression of retinopathy with intensive versus conventional treatment in the Diabetes Control and Complications Trial. Diabetes Control and Complications Trial Research Group. Ophthalmology 95; 102(4):647-61.
Not in an outpatient setting

Anon. Psychological aspects of continuous glucose monitoring in pediatric type 1 diabetes. Pediatr Diabetes 2006; 7(1):32-8.
Other reason

Anon. Risk of hypoglycaemia in types 1 and 2 diabetes: effects of treatment modalities and their duration. Diabetologia 2007; 50(6):1140-7.
Does not evaluate CSII or rt-CGM

Anon. Strict metabolic control and eye and kidney function in diabetes. Lancet 82; 1(8272):630-1.
No original data

Anon. The effect of intensive diabetes therapy on the development and progression of neuropathy. The Diabetes Control and Complications Trial Research Group. Ann Intern Med 95; 122(8):561-8.
Does not evaluate CSII or rt-CGM

Anon. Update: deaths among patients using continuous subcutaneous insulin infusion pumps--United States. MMWR Morb Mortal Wkly Rep 82; 31(46):625-6.
No original data

Arias, P., Kerner, W., de la Fuente, A., and Pfeiffer, E. F. Abnormal growth hormone levels in insulin-dependent diabetic patients under continuous subcutaneous insulin infusion and intensified conventional treatment. Acta Endocrinol (Copenh) 84; 107(2):250-5.
No comparison with placebo or usual care

Arias, P., Kerner, W., Zier, H., Navascues, I., and Pfeiffer, E. F. Incidence of hypoglycemic episodes in diabetic patients under continuous subcutaneous insulin infusion and intensified conventional insulin treatment: assessment by means of semiambulatory 24-hour continuous blood glucose monitoring. Diabetes Care 85; 8(2):134-40.
Less than 24 hours of usage

Arlot, S., Lalau, J. D., Mesmacque, A., and Quichaud, J. [Remission of recently-appearing insulin-dependent diabetes mellitus: value of continuous infusion of insulin]. LARC Med 84; 4(8):475-8.
No original data

Aucott, S. W., Williams, T. G., Hertz, R. H., and Kalhan, S. C. Rigorous management of insulin-dependent diabetes mellitus during pregnancy. Acta Diabetol 94; 31(3):126-9.
No formal diagnosis of diabetes

Bak, J. F., Nielsen, O. H., Pedersen, O., and Beck-Nielsen, H. Multiple insulin injections using a pen injector versus insulin pump treatment in young diabetic patients. Diabetes Res 87; 6(3):155-8.
No concurrent comparison group

Barbosa, J. and Johnson, S. Severe hypoglycemia during maximized insulin treatment of diabetes in a randomized clinical trial. Diabetes Care 83; 6(1):62-3.
Case series or cross-sectional

Barbosa, J. Treatment with insulin pumps is no better than intensive conventional treatment. BR. MED. J. 84; 288(6436):51.
No original data

Barnard, K. D. and Skinner, T. C. Cross-sectional study into quality of life issues surrounding insulin pump use in type 1 diabetes. Pract. Diabetes Int. 2008; 25(5):194-200.
Case series or cross-sectional

Bastiaensen, L. Effect of continuous subcutaneous insulin infusion on retinopathy. Br J Ophthalmol 83; 67(7):491-2.
No original data

Baum, C. R. "Toxic shock:" can playground static cause insulin pump failure?. Ann Emerg Med 2007; 49(1):113.
Case series or cross-sectional

Beau, P., Marechaud, R., and Matuchansky, C. Cyclic total parenteral nutrition, diabetes mellitus, and subcutaneous insulin pump. Lancet 86; 1(8492):1272-3.
No comparison with placebo or usual care

Beck, R. W., Hirsch, I. B., Laffel, L., Tamborlane, W. V., Bode, B. W., Buckingham, B., Chase, H. P., et al. Juvenile diabetes research foundation continuous glucose monitoring study group. The effect of continuous glucose monitoring in well-controlled type 1 diabetes (Diabetes Care (2009) 32, (1378-1383)). Diabetes Care 2009; 32(10):1944.
Other reason

Becker, D. I. Pediatric use of insulin pumps: longer infusion site lifetime with NovoLog. Diabetes Care 2002; 25(9):1663.
Case series or cross-sectional

Beck-Nielsen, H., Olesen, T., Mogensen, C. E., Richelsen, B., Olsen, H. W., Ehlers, N., Charles, P., and Sorensen, N. S. Effect of near normoglycemia for 5 years on progression of early diabetic retinopathy and renal involvement. Diabetes Res 90; 15(4):185-90.
No comparison with placebo or usual care

Beck-Nielsen, H., Richelsen, B., Mogensen, C. E., Olsen, T., Ehlers, N., Nielsen, C. B., and Charles, P. Effect of insulin pump treatment for one year on renal function and retinal morphology in patients with IDDM. Diabetes Care 85; 8(6):585-9.
No comparison with placebo or usual care

Beck-Nielsen, H., Richelsen, B., Schwartz Sorensen, N., and Hother Nielsen, O. Insulin pump treatment: effect on glucose homeostasis, metabolites, hormones, insulin antibodies and quality of life. Diabetes Res 85; 2(1):37-43.
No comparison with placebo or usual care

Behme, M. T. and Dupre, J. Insulin-binding to erythrocytes in type I diabetes mellitus: effects of continuous subcutaneous infusion of insulin. Clin Invest Med 84; 7(2):109-14.
No comparison with placebo or usual care

Belicar, P. and Lassmann-Vague, V. Local adverse events associated with long-term treatment by implantable insulin pumps. The French EVADIAC Study Group experience. Evaluation dans le Diabete du Traitement par Implants Actifs. Diabetes Care 98; 21(2):325-6.
Case series or cross-sectional

Belicar, P., Lassman-Vague, V., Gin, H., Catargi, B., Charpentier, G., Deburge, A., Brun, J.-M., Pacaud-Brun, A., Rocher-Mingret, L., Gilly, F., Vague, P., Bringer, J., Renard, E., Drouin, P., Guerci, B., Meyer, L., Slama, G., Selam, J.-L., Haardt M.-, J. Local adverse events associated with long-term treatment by implantable insulin pumps [2]. Diabetes Care 98; 21(2):325-326.
No concurrent comparison group

Bell PM, Hayes JR, and Hadden DR A comparison of continuous subcutaneous insulin infusion (CSII) and conventional therapy in insulin dependent diabetes mellitus (IDDM) [abstract]. Ir-J-Med-Sci 84; 153(3):116.
Case series or cross-sectional

Bell, P. M., Hayes, J. R., Hadden, D. R., and Archer, D. B. The effect of plasma glucose control by continuous subcutaneous insulin infusion or conventional therapy on retinal morphology and urinary albumin excretion. Diabete Metab 85; 11(4):254-61.
No comparison with placebo or usual care

Bell, P. M., Sawhney, B., Hayes, J. R., and Hadden, D. R. Effect of plasma glucose control by continuous subcutaneous insulin infusion on nerve conduction. Ir J Med Sci 85; 154(10):378-84.
No comparison with placebo or usual care

Bending, J. J., Pickup, J. C., and Keen, H. Frequency of diabetic ketoacidosis and hypoglycemic coma during treatment with continuous subcutaneous insulin infusion. Audit of medical care. Am J Med 85; 79(6):685-91.
No original data

Bending, J. J., Pickup, J. C., and Keen, H. Treatment with insulin pumps versus intensive conventional treatment. BR. MED. J. 84; 289(644 O):320-321.
No original data

Bergenstal, R. M., Morse, P., Rubenstein, A. H., Bending, J. J., Bilous, R. W., Keen, H., Pickup, J. C., et al. Diabetic retinopathy after two years of intensified insulin treatment. Follow-up of the Kroc Collaborative Study. J. AM. MED. ASSOC. 88; 260(1):37-41.
No comparison with placebo or usual care

Berger, M., Sonnenberg, E., Chantelau, E. A., and Best, F. [Treatment of insulin-dependent diabetes by continuous sub-cutaneous insulin perfusion]. Journ Annu Diabetol Hotel Dieu 84; :175-82.
Other reason

Berger, M., Sonnenberg, G., and Chantelau, E. A. Steno Study Group trial of continuous subcutaneous insulin. Lancet 82; 1(8276):860.
No original data

Berger, W., Keller, U., Straumann, M., Clerc, D., and Fried, M. [Long-term use of portable insulin pumps to stabilize metabolism in labile diabetics and for euglycemic blood sugar regulation in pregnancy]. Schweiz Med Wochenschr 83; 113(18):679-88.
Case series or cross-sectional

Berghaeuser, M. A., Kapellen, T., Heidtmann, B., Haberland, H., Klinkert, C., and Holl, R. W. Continuous subcutaneous insulin infusion in toddlers starting at diagnosis of type 1 diabetes mellitus. A multicenter analysis of 104 patients from 63 centres in Germany and Austria. Pediatr Diabetes 2008; 9(6):590-5.
No comparison with placebo or usual care

Bergis, K. H. [Patients' experiences with insulin lispro in daily use. Yesterday's innovation--today's standard therapy]. Krankenpfl J 99; 37(9):347-9.
No original data

Bergis, K., Otto, K., and Mann, M. [Painful polyneuropathy in type I diabetes: intermediate insulin-pump therapy]. Dtsch Med Wochenschr 86; 111(12):477-8.
Case series or cross-sectional

Bergman, M. and Felig, P. Newer approaches to the control of the insulin-dependent diabetic patient. Dis Mon 83; 29(7):Jan-65.
No original data

Bergua, M., Levy, I., Casamitjana, R., and Figuerola, D. [Therapeutic hyperinsulinism induced by the use of continuous insulin infusion pumps and the artificial pancreas in diabetic patients]. Med Clin (Barc) 83; 81(6):243-5.
Other reason

Berkeley, J., Lunt, H., and Frampton, C. Efficacy of continuous subcutaneous insulin infusion (CSII) in patients with classical contraindications to its use. Diabet Med 2007; 24(12):1496-7.
No comparison with placebo or usual care

Bernsmeier, H. and Sonnenberg, G. E. [Diabetic retinopathy with continuous subcutaneous insulin infusion therapy (insulin pump)]. Fortschr Ophthalmol 84; 81(3):267-70.
Case series or cross-sectional

Bernsmeier, H., Cicmir, I., Koschinski, T., and Gries, F. A. [Comparison of the development of retinopathy in treatment with the insulin pump and intensified conventional therapy]. Fortschr Ophthalmol 86; 83(4):467-70.
No comparison with placebo or usual care

Berthe, E., Lireux, B., Coffin, C., Goulet-Salmon, B., Houlbert, D., Boutreux, S., Fradin, S., and Reznik, Y. Effectiveness of intensive insulin therapy by multiple daily injections and continuous subcutaneous infusion: a comparison study in type 2 diabetes with conventional insulin regimen failure. Horm Metab Res 2007; 39(3):224-9.
Other reason

Bibergeil, H., Huttl, I., Felsing, W., Felsing, U., Seidlein, I., Herfurth, S., Dabels, J., Reichel, G., Luder, C., Albrecht, G., and et, a. l. 36 months continuous subcutaneous insulin infusion (CSII) in insulin dependent diabetes (IDDM)--influence on early stages of retinopathy, nephropathy and neuropathy--psychological analysis. Exp Clin Endocrinol 87; 90(1):51-61.
No concurrent comparison group

Biesenbach, G., Grafinger, P., Kaiser, W., Stuby, U., and Zazgornik, J. [Metabolic control in labile type I diabetes with conventional insulin therapy, basal bolus insulin therapy using pens and continuous subcutaneous insulin infusion with the pump]. Med Klin (Munich) 88; 83(12):398-401.
No concurrent comparison group

Bin-Abbas, B. S. Insulin pump therapy during Ramadan fasting in type 1 diabetic adolescents. Ann Saudi Med 2008; 28(4):305-6.
No comparison with placebo or usual care

Bin-Abbas, B. S., Al-Fares, A., Sakati, N. A., and Al-Ashwal, A. A. Comparison of insulin pump and multiple daily injection regimens in type 1 diabetic patients. Curr. Paediatr. Res. 2006; 10(02-Jan):37-39.
Other reason

Bin-Abbas, B. S., Sakati, N. A., and Al-Ashwal, A. A. Glycemic control and treatment satisfaction in Saudi diabetic children on insulin pump therapy [5]. Ann. Saudi Med. 2006; 26(3):247-248.
No concurrent comparison group

Bin-Abbas, B. S., Sakati, N. A., and Al-Ashwal, A. A. Glycemic control and treatment satisfaction in Saudi diabetic children on insulin pump therapy. Ann Saudi Med 2006; 26(5):405.
No concurrent comparison group

Birman, P. [Conventional insulin therapy, infusion pumps, injector syringes. Different methods of administration]. Soins 89; (524):30-5.
No original data

Blackett, P. R. Insulin pump treatment for recurrent ketoacidosis in adolescence. Diabetes Care 95; 18(6):881-2.
Case series or cross-sectional

Bloomgarden, Z. T. Aspects of insulin treatment. Diabetes Care 2010; 33(1):e1-6.
No original data

Bode, B. W. Clinical utility of the continuous glucose monitoring system. Diabetes Technol Ther 2000; 2 Suppl 1:S35-41.
Case series or cross-sectional

Boizel, R., Benhamou, P. Y., and Renard, E. Glucose monitoring and pump data management software operated on a personal digital assistant can contribute to improve diabetes control in CSII-treated patients. Diabetes Metab 2007; 33(4):314-5.
Does not evaluate CSII or rt-CGM

Boland, E. A flexible option for adolescents with diabetes. Insulin pump therapy. Adv Nurse Pract 98; 6(2):38-44.
No original data

Boland, E. A. and Tamborlane, W. V. Continuous glucose monitoring in youth with type 2 diabetes: overcoming barriers to successful treatment. Diabetes Technol Ther 2000; 2 Suppl 1:S53-9.
No original data

Boland, E. A., Grey, M., Oesterle, A., Fredrickson, L., and Tamborlane, W. V. Continuous subcutaneous insulin infusion. A new way to lower risk of severe hypoglycemia, improve metabolic control, and enhance coping in adolescents with type 1 diabetes. Diabetes Care 99; 22(11):1779-84.
Regular insulin was used in the pump

Bonfanti, R., Meschi, F., Viscardi, M., Rigamonti, A., Biffi, V., Frontino, G., Battaglino, R., Favalli, V., Bonura, C., and Chiumello, G. Long-term efficacy of insulin pump therapy in young children with diabetes. Diabetologia 2010; 53:S372.
Case series or cross-sectional

Borisova, A. M., Koev, D., and Kirilov, G. [An improvement in insulin efficacy in patients with type-1 diabetes mellitus following treatment using an insulin infusion pump]. Vutr Boles 89; 28(1):74-7.
Regular insulin was used in the pump

Botta, R. M., Sinagra, D., Angelico, M. C., and Bompiani, G. D. [Comparison of intensified traditional insulin therapy and micropump therapy in pregnant women with type 1 diabetes mellitus]. Minerva Med 86; 77(17):657-61.
Regular insulin was used in the pump

Bougneres, P. F. [Are there indications for treatment with the insulin pump in pediatrics?]. Diabete Metab 85; 11(5):320-1.
No original data

Bougneres, P. F. [Intensive insulin therapy in the diabetic child]. Union Med Can 85; 114(10):821-8.
No original data

Bouhanick, B., Biquard, F., Hadjadj, S., and Roques, M. A. Does treatment with antenatal glucocorticoids for the risk of premature delivery contribute to ketoacidosis in pregnant women with diabetes who receive continuous subcutaneous insulin infusion (CSII)?. Arch Intern Med 2000; 160(2):242-3.
Case series or cross-sectional

Boulton, A. J. M., Drury, J., and Ward, J. D. Treatment of painful and ulcerative diabetic neuropathy by continuous subcutaneous insulin infusion (CSII). DIABETOLOGIA 81; 21(3):67.
Other reason

Bourgon, C. [Subcutaneous insulin pumps]. Soins 91; (548):29-30, 32-4.
Other reason

Bozzetti, V., Viscardi, M., Bonfanti, R., Azzinari, A., Meschi, F., Bognetti, E., and Chiumello, G. Results of continuous glucose monitoring by GlucoWatch Biographer in a cohort of diabetic children and adolescents under real-life conditions. Pediatr Diabetes 2003; 4(1):57-8.
No original data

Bradley, C. On calculating treatment satisfaction. Diabetes Care 99; 22(10):1760.
Case series or cross-sectional

Bradley, C., Gamsu, D. S., Knight, G., Boulton, A. J., and Ward, J. D. Predicting risk of diabetic ketoacidosis in patients using continuous subcutaneous insulin infusion. Br Med J (Clin Res Ed) 86; 293(6541):242-3.
Does not evaluate CSII or rt-CGM

Bragd, J., Adamson, U., Lins, P.-E., Dobeln, A. V., and Oskarsson, P. Basal insulin substitution with glargine or CSII in adult type 1 diabetes patients - A randomized controlled trial. Diabetes 2009; 58:.
Case series or cross-sectional

Bragd, J., von Dobeln, A., Lins, P. E., Adamson, U., Bergstrom, J., and Oskarsson, P. Basal insulin substitution with glargine or continuous subcutaneous insulin infusion in adult type 1 diabetes patients-a randomized controlled trial. Diabetes Technol Ther 2010; 12(9):689-93.
No comparison with placebo or usual care

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No original data

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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No original data

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No original data

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Case series or cross-sectional

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Not in an outpatient setting

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Other reason

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Not in an outpatient setting

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Not in an outpatient setting

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Other reason

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No comparison with placebo or usual care

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Other reason

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No original data

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Case series or cross-sectional

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Regular insulin was used in the pump

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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Does not evaluate CSII or rt-CGM

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No concurrent comparison group

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Other reason

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Does not apply to a key question

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Regular insulin was used in the pump

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Does not evaluate CSII or rt-CGM

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Regular insulin was used in the pump

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No original data

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No concurrent comparison group

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No comparison with placebo or usual care

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Does not evaluate CSII or rt-CGM

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Case series or cross-sectional

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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Case series or cross-sectional

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Case series or cross-sectional

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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No comparison with placebo or usual care

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No original data

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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Other reason

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No original data

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No concurrent comparison group

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Other reason

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No original data

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Does not apply to a key question

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Other reason

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Does not apply to a key question

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Regular insulin was used in the pump

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No comparison with placebo or usual care

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Case series or cross-sectional

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No comparison with placebo or usual care

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No concurrent comparison group

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Case series or cross-sectional

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Case series or cross-sectional

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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No original data

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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No comparison with placebo or usual care

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No original data

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No comparison with placebo or usual care

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Other reason

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No original data

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No original data

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Case series or cross-sectional

Fish, L. H., Wetzler, H. P., Davidson, J. L., Ofstead, C. L., and Johnson, M. L. Advanced Insulin Management program reduces A1C levels and regimen-related distress without weight gain in patients with type 1 diabetes mellitus. Insulin 2008; 3(2):59-66.
Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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No original data

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Regular insulin was used in the pump

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No comparison with placebo or usual care

Fox, L., Englert, K., and Mauras, N. Effects of continuous subcutaneous insulin infusion (CSII) in adolescents with newly-diagnosed type 1 diabetes (T1D) on insulin resistance and ss-cell function: A pilot study. Diabetes 2009; 58:.
Case series or cross-sectional

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No comparison with placebo or usual care

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No original data

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Regular insulin was used in the pump

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No original data

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Other reason

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Does not evaluate CSII or rt-CGM

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No comparison with placebo or usual care

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No original data

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No comparison with placebo or usual care

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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No original data

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No original data

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Case series or cross-sectional

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Regular insulin was used in the pump

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Other reason

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Other reason

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No comparison with placebo or usual care

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Other reason

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Other reason

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Regular insulin was used in the pump

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Case series or cross-sectional

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Regular insulin was used in the pump

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No concurrent comparison group

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Case series or cross-sectional

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Case series or cross-sectional

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No concurrent comparison group

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Case series or cross-sectional

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No comparison with placebo or usual care

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Does not evaluate CSII or rt-CGM

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Does not evaluate CSII or rt-CGM

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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Case series or cross-sectional

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No comparison with placebo or usual care

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Does not evaluate CSII or rt-CGM

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No comparison with placebo or usual care

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Does not apply to a key question

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No concurrent comparison group

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No original data

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No original data

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No comparison with placebo or usual care

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No concurrent comparison group

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Regular insulin was used in the pump

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No comparison with placebo or usual care

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No original data

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Case series or cross-sectional

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Other reason

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No original data

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No original data

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No original data

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No original data

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No comparison with placebo or usual care

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Case series or cross-sectional

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No original data

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Regular insulin was used in the pump

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No original data

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Case series or cross-sectional

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Regular insulin was used in the pump

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Case series or cross-sectional

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Regular insulin was used in the pump

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Does not evaluate CSII or rt-CGM

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Does not evaluate CSII or rt-CGM

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Regular insulin was used in the pump

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No original data

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No original data

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No concurrent comparison group

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Regular insulin was used in the pump

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No comparison with placebo or usual care

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No original data

Jean, R. and Rolin, B. [Continuous predetermined insulin infusion in insulin-dependent diabetes, mellitus (author's transl)]. Ann Pediatr (Paris) 81; 28(7):481-3.
Other reason

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Other reason

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Case series or cross-sectional

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No comparison with placebo or usual care

Jia, W. P. [Information changes recognition: clinical use of continuous glucose monitoring system]. Zhonghua Yi Xue Za Zhi 2009; 89(10):649-50.
Other reason

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Regular insulin was used in the pump

Johansson, B. L., Berg, U., Broberger, O., and Thalme, B. [Improved metabolic control, kidney function and health care economics are the results of treatment with insulin pump]. Lakartidningen 83; 80(41):3818-20.
Regular insulin was used in the pump

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Case series or cross-sectional

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No original data

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No original data

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Other reason

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No concurrent comparison group

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Regular insulin was used in the pump

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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Case series or cross-sectional

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No original data

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Case series or cross-sectional

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Does not evaluate CSII or rt-CGM

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No original data

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No original data

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Other reason

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No original data

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No original data

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No original data

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No concurrent comparison group

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No original data

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Other reason

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No original data

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No comparison with placebo or usual care

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No original data

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Does not evaluate CSII or rt-CGM

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No concurrent comparison group

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Case series or cross-sectional

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No comparison with placebo or usual care

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Does not apply to a key question

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Does not apply to a key question

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Other reason

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No original data

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Case series or cross-sectional

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Other reason

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Other reason

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Case series or cross-sectional

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No comparison with placebo or usual care

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No original data

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Other reason

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No comparison with placebo or usual care

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Case series or cross-sectional

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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Case series or cross-sectional

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Other reason

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No original data

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Case series or cross-sectional

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No concurrent comparison group

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No comparison with placebo or usual care

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Regular insulin was used in the pump

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Not in an outpatient setting

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Other reason

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No original data

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Does not apply to a key question

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No comparison with placebo or usual care

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No concurrent comparison group

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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Does not evaluate CSII or rt-CGM

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No concurrent comparison group

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Case series or cross-sectional

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Other reason

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Other reason

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Does not apply to a key question

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No original data

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No original data

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No concurrent comparison group

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No outcome of interest

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No concurrent comparison group

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No original data

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Case series or cross-sectional

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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Case series or cross-sectional

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No comparison with placebo or usual care

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No original data

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No original data

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No concurrent comparison group

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No comparison with placebo or usual care

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Does not apply to a key question

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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Not in an outpatient setting

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No comparison with placebo or usual care

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No original data

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Other reason

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Case series or cross-sectional

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No comparison with placebo or usual care

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Does not evaluate CSII or rt-CGM

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Other reason

Mirouze, J., Selam, J. L., Rodier, M., Lapinski, H., Saeidi, C., and Richard, J. L. [Treatment of diabetes mellitus with insulin infusions]. Bull Acad Natl Med 84; 168(02-Jan):80-90.
Other reason

Mitka, M. Poor patient adherence may undermine aim of continuous glucose monitoring. JAMA 2007; 298(6):614-5.
No original data

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Case series or cross-sectional

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No comparison with placebo or usual care

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No original data

Montana, E., Ricart, W., Virgili, N., and Fernandez Castaner, M. [Unstable diabetes and continuous insulin infusion pump]. Med Clin (Barc) 86; 87(6):262.
Case series or cross-sectional

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No comparison with placebo or usual care

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Other reason

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Not in an outpatient setting

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Does not evaluate CSII or rt-CGM

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No comparison with placebo or usual care

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

Nabhan, Z. M., Kreher, N. C., Greene, D. M., Eugster, E. A., Kronenberger, W., and DiMeglio, L. A. A randomized prospective study of insulin pump vs. insulin injection therapy in very young children with type 1 diabetes: 12-month glycemic, BMI, and neurocognitive outcomes. Pediatr Diabetes 2009; 10(3):202-8.
No comparison with placebo or usual care

Nathan, D. M., Lou, P., and Avruch, J. Intensive conventional and insulin pump therapies in adult type I diabetes. A crossover study. Ann Intern Med 82; 97(1):31-6.
Other reason

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Case series or cross-sectional

Neff, K., McCarthy, A., Forde, R., Foley, M., Coulter-Smith, S., Daly, S., Firth, R., Byrne, M. M., and Kinsley, B. T. Intensive glycaemic control in type 1 diabetic pregnancy: A comparison of continuous subcutaneous insulin infusion and multiple daily injection therapy. Diabetologia 2010; 53:S433.
Case series or cross-sectional

Newman, S. P., Cooke, D., Casbard, A., Walker, S., Meredith, S., Nunn, A., Steed, L., Manca, A., Sculpher, M., Barnard, M., Kerr, D., Weaver, J., Ahlquist, J., and Hurel, S. J. A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). Health Technol Assess 2009; 13(28):iii-iv, ix-xi, 1-194.
Does not evaluate CSII or rt-CGM

Ng Tang Fui, S., Pickup, J. C., Bending, J. J., Collins, A. C., Keen, H., and Dalton, N. Hypoglycemia and counterregulation in insulin-dependent diabetic patients: a comparison of continuous subcutaneous insulin infusion and conventional insulin injection therapy. Diabetes Care 86; 9(3):221-7.
No comparison with placebo or usual care

Nicolino, M., Sulmont, V., Bendelac, N., Reznik, Y., Guerci, B., Renard, E., Hanaire, H., Jeandidier, N., and Raccah, D. The RealTrend Study: Effect of continuous glucose monitoring on metabolic control in addition to pump therapy in poorly controlled type 1 diabetic patients. Pediatr. Diabetes 2009; 10:105.
Case series or cross-sectional

Nicolucci, A., Maione, A., Franciosi, M., Amoretti, R., Busetto, E., Capani, F., Bruttomesso, D., Di Bartolo, P., Girelli, A., Leonetti, F., Morviducci, L., Ponzi, P., and Vitacolonna, E. Quality of life and treatment satisfaction in adults with Type 1 diabetes: a comparison between continuous subcutaneous insulin infusion and multiple daily injections. Diabet Med 2008; 25(2):213-20.
Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

Norgaard, K. [Use of insulin pumps in Denmark]. Ugeskr Laeger 2003; 165(23):2380-2.
Other reason

Nosadini, R., Velussi, M., Fioretto, P., Doria, A., Avogaro, A., Trevisan, R., Valerio, A., Vizzaccaro, A., Bruscagnin, A., Cernigoi, A., Pascoletti, R., Bernardi, G., Duner, E., Da Campo, G. L., and Costella, G. B. Frequency of hypoglycaemic and hyperglycaemic-ketotic episodes during conventional and subcutaneous continuous insulin infusion therapy in IDDM. DIABETES NUTR. METAB. CLIN. EXP. 88; 1(4):289-296.
No comparison with placebo or usual care

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Regular insulin was used in the pump

Noto, R. A., Ginsberg, L., Lifshitz, F., Pelcovitz, D., and Kaplan, S. Improved management of brittle-psychosocial diabetes by use of a portable insulin infusion pump. J Pediatr 85; 107(1):100-2.
Case series or cross-sectional

O'Brien, B. Continuous glucose monitoring improved glycaemic control in pregnant women with diabetes and reduced infant macrosomia. Evid Based Nurs 2009; 12(2):43.
Does not apply to a key question

Olohan, K. and Zappitelli, D. The insulin pump. Am J Nurs 2003; 103(4):48-56; quiz 57.
No original data

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Does not apply to a key question

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No comparison with placebo or usual care

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No concurrent comparison group

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Other reason

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Other reason

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Other reason

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Does not evaluate CSII or rt-CGM

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Case series or cross-sectional

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No concurrent comparison group

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Other reason

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No concurrent comparison group

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Case series or cross-sectional

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Case series or cross-sectional

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Case series or cross-sectional

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Case series or cross-sectional

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No concurrent comparison group

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Case series or cross-sectional

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Case series or cross-sectional

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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Case series or cross-sectional

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Does not evaluate CSII or rt-CGM

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No original data

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No concurrent comparison group

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Other reason

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Other reason

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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No concurrent comparison group

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No original data

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No comparison with placebo or usual care

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Does not evaluate CSII or rt-CGM

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Case series or cross-sectional

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Other reason

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No comparison with placebo or usual care

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Case series or cross-sectional

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Other reason

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Other reason

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No original data

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Regular insulin was used in the pump

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No original data

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No concurrent comparison group

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No concurrent comparison group

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No concurrent comparison group

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Regular insulin was used in the pump

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Regular insulin was used in the pump

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No original data

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Regular insulin was used in the pump

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Less than 24 hours of usage

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Regular insulin was used in the pump

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No comparison with placebo or usual care

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No comparison with placebo or usual care

Schwedes, U. [Insulin therapy with pens and pumps]. Med Klin (Munich) 96; 91 Suppl 1:16.
No original data

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No original data

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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Other reason

Selam, J. L., Millet, P., Zaluski, S., and Mirouze, J. [Beneficial effect of insulin therapy by pump on the development of diabetic retinopathy]. Journ Annu Diabetol Hotel Dieu 85; :87-100.
No comparison with placebo or usual care

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No comparison with placebo or usual care

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No original data

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Other reason

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No comparison with placebo or usual care

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Does not evaluate CSII or rt-CGM

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Case series or cross-sectional

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Does not evaluate CSII or rt-CGM

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Not in an outpatient setting

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No concurrent comparison group

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Does not evaluate CSII or rt-CGM

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No comparison with placebo or usual care

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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No original data

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No original data

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No comparison with placebo or usual care

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Does not evaluate CSII or rt-CGM

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Not in an outpatient setting

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Other reason

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Regular insulin was used in the pump

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Case series or cross-sectional

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No concurrent comparison group

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No original data

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Does not apply to a key question

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Other reason

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No original data

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No concurrent comparison group

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Regular insulin was used in the pump

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Case series or cross-sectional

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Other reason

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No comparison with placebo or usual care

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No original data

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Case series or cross-sectional

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No concurrent comparison group

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No original data

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No comparison with placebo or usual care

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Case series or cross-sectional

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Does not apply to a key question

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Case series or cross-sectional

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Does not evaluate CSII or rt-CGM

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Case series or cross-sectional

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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No original data

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Case series or cross-sectional

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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Observational study that does not report on macrovascular, microvascular, maternal, or fetal outcomes

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No original data

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No comparison with placebo or usual care

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No comparison with placebo or usual care

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Regular insulin was used in the pump

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No concurrent comparison group

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No outcome of interest

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Other reason

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Does not apply to a key question

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No original data

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No original data

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No concurrent comparison group

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Case series or cross-sectional

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Other reason

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No concurrent comparison group

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No comparison with placebo or usual care

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Case series or cross-sectional

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Case series or cross-sectional

Valenzuela, J. M., Patino, A. M., McCullough, J., Ring, C., Sanchez, J., Eidson, M., Nemery, R., and Delamater, A. M. Insulin pump therapy and health-related quality of life in children and adolescents with type 1 diabetes. J Pediatr Psychol 2006; 31(6):650-60.
No comparison with placebo or usual care

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Other reason

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Case series or cross-sectional

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No comparison with placebo or usual care

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No concurrent comparison group

Van Ballegooie, E., Visser, G. H., and Laurini, R. N. Continuous subcutaneous insulin infusion (CSII) in pregnancy. Neth J Med 85; 28 Suppl 1:06-Mar.
No comparison with placebo or usual care

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Other reason

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No outcome of interest

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Other reason

Vanelli, M., Bernasconi, S., Rossi, S., Rocca, M., Turni, A., and Giovannelli, G. [Treatment of diabetic ketoacidosis in children]. Arch Fr Pediatr 82; 39(4):203-7.
Other reason

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Case series or cross-sectional

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No concurrent comparison group

Vavrinec, J., Lebl, J., Zizkovsky, V., Dvorak, P., and Snajderova, M. [Changes in insulin resistance in diabetic children after treatment with an insulin pump]. Cesk Pediatr 87; 42(7):411-5.
Other reason

Viberti, G. C., Bilous, R. W., Mackintosh, D., Bending, J. J., and Keen, H. Long term correction of hyperglycaemia and progression of renal failure in insulin dependent diabetes. Br Med J (Clin Res Ed) 83; 286(6365):598-602.
No comparison with placebo or usual care

Vozar, J., Kusinova, F., Komornik, J., Mikulecky, M., and Ondrejka, P. [Comparison of the effects of conventional insulin therapy and the insulin infusion pump on blood glucose values in pregnant diabetics]. Bratisl Lek Listy 86; 85(5):570-7.
Case series or cross-sectional

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Case series or cross-sectional

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No concurrent comparison group

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No comparison with placebo or usual care

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Does not evaluate CSII or rt-CGM

Ward, J. D. Continuous subcutaneous insulin infusion (CSII): therapeutic options. Diabet Med 84; 1(1):47-50.
No original data

Warmolts, J. R., Mendell, J. R., O'Dorisio, T. M., and Cataland, S. Comparison of the effects of continuous subcutaneous infusion and split-mixed injection of insulin on nerve function in type I diabetes mellitus. J Neurol Sci 87; 82(03-Jan):161-9.
No comparison with placebo or usual care

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No concurrent comparison group

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No concurrent comparison group

Welsh, J. B., Kannard, B., Nogueira, K., Kaufman, F. R., and Shah, R. Insights from a Large Observational Database of Continuous Glucose Monitoring Adoption, Insulin Pump Usage and Glycemic Control: The CareLink Database. Pediatr Endocrinol Rev 2010; 7 Suppl 3:413-6.
No comparison with placebo or usual care

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Regular insulin was used in the pump

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Does not apply to a key question

Whittemore, R., Jeon, S., Jaser, S., Liberti, L., Cahill, J., and Grey, M. Quality of life and metabolic control in school-aged children with type 1 diabetes. Diabetes 2009; 58:.
Case series or cross-sectional

Wilke, W. and Huttl, I. [Portable infusion pumps for insulin administration in type I diabetic patients]. Z Arztl Fortbild (Jena) 89; 83(9):449-53.
No original data

Wilkinson, J., McFann, K., and Chase, H. P. Factors affecting improved glycaemic control in youth using insulin pumps. Diabet Med 2010; 27(10):1174-7.
No comparison with placebo or usual care

Williams, S., Honeywell, M., Hill, A., Singh, A., and Ghazvini, P. The Guardian REAL-TIME continuous glucose monitoring system. 2007; 32(12):62-65.
No original data

Wilson, D. M., Buckingham, B. A., Kunselman, E. L., Sullivan, M. M., Paguntalan, H. U., and Gitelman, S. E. A two-center randomized controlled feasibility trial of insulin pump therapy in young children with diabetes. Diabetes Care 2005; 28(1):15-9.
No outcome of interest

Wilson, D. P. and Endres, R. K. Continuous subcutaneous insulin infusion (CSII). J Okla State Med Assoc 85; 78(7):211-4.
Does not apply to a key question

Wilson, M. A. and Smith, C. B. Nutrient intake, glycemic control, and body mass index in adolescents using continuous subcutaneous insulin infusion and those using traditional insulin therapy. Diabetes Educ 2003; 29(2):230-2, 235-6, 238.
Other reason

Wolff-McDonagh, P., Kaufmann, J., Foreman, S., Wisotsky, S., Wisotsky, J. A., and Wexler, C. Using insulin pump therapy in poorly controlled type 2 diabetes. Diabetes Educ 2010; 36(4):657-65.
No comparison with placebo or usual care

Worm, D., Nielsen, L. R., Mathiesen, E. R., and Norgaard, K. Continuous glucose monitoring system with an alarm: a tool to reduce hypoglycemic episodes in pregnancy with diabetes. Diabetes Care 2006; 29(12):2759-60.
Case series or cross-sectional

Wredling, R. A., Adamson, U. K., and Lins, P. E. Alteration of the risk factor paradigm for discontinuance of insulin pump therapy. Diabetes Care 94; 17(8):942-3.
Case series or cross-sectional

Wu, Y. P., Graves, M. M., Roberts, M. C., and Mitchell, A. C. Is insulin pump therapy better than injection for adolescents with diabetes?. Diabetes Res Clin Pract 2010; 89(2):121-5.
Case series or cross-sectional

Wyatt, S. Technology useful in managing diabetes during pregnancy. Aust Nurs J 2008; 16(2):34.
No comparison with placebo or usual care

Yagasaki, H., Kobayashi, K., Saitou, T., Nagamine, K., Mitsui, Y., Mochizuki, M., Kobayashi, K., Cho, H., Ohyama, K., Amemiya, S., and Nakazawa, S. Nocturnal blood glucose and IGFBP-1 changes in type 1 diabetes: Differences in the dawn phenomenon between insulin regimens. Exp Clin Endocrinol Diabetes 2010; 118(3):195-9.
Not in an outpatient setting

Yamaguchi, T., Kanatsuka, A., Hashimoto, N., Makino, H., and Yoshida, S. Influence of age on insulin requirement in insulin dependent diabetes mellitus patients treated with CSII. Horm Metab Res 86; 18(11):786-7.
No comparison with placebo or usual care

Yoo, H. J., An, H. G., Park, S. Y., Ryu, O. H., Kim, H. Y., Seo, J. A., Hong, E. G., Shin, D. H., Kim, Y. H., Kim, S. G., Choi, K. M., Park, I. B., Yu, J. M., and Baik, S. H. Use of a real time continuous glucose monitoring system as a motivational device for poorly controlled type 2 diabetes. Diabetes Res Clin Pract 2008; 82(1):73-9.
Other reason

Yudkin, J. S. Insulin infusion in diabetic patients with acute myocardial infarction. Insulin should be continued for 12 months after acute event. BMJ 97; 314(7074):145-6.
No original data

Zaluski, S., Calvet, L., Selam, J. L., Mirouze, J., and Martin, G. [Vitreous fluorophotometry in diabetics using an insulin pump: absent or minimal retinopathy]. Ophtalmologie 88; 2(2):101-4.
Other reason

Zaluski, S., Millet, P., and Selam, J. L. [Course of the proliferative forms of diabetic retinopathy in patients with insulin pump]. Ophtalmologie 87; 1(3):393-5.
Other reason

Zaluski, S., Millet, P., Selam, J. L., Navarre, L., Esmenjaud, E., and Karsenti, G. [Course of diabetic retinopathy under the insulin pump]. Bull Soc Ophtalmol Fr 85; 85(5):601-13.
No comparison with placebo or usual care

Ziegler, D., Dannehl, K., Koschinsky, T., Toeller, M., and Gries, F. A. Comparison of continuous subcutaneous insulin infusion and intensified conventional therapy in the treatment of Type I diabetes: A two-year randomized study. DIABETES NUTR. METAB. CLIN. EXP. 90; 3(3):203-213.
No comparison with placebo or usual care

Zisser, H. and Jovanovic, L. OmniPod Insulin Management System: patient perceptions, preference, and glycemic control. Diabetes Care 2006; 29(9):2175.
No comparison with placebo or usual care

Table 1. Study design characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Study design Run in period Support	Enrollment dates Followup duration	Location	N enrolled (N Screened) Source population	Included population	Exclusion criteria
Beck, 2010[71]	RCT, parallel arms	Enrollment NR 26 wks	NR	451 (NR) Source population:	T1DM, very young, adults, elderly	NR
Bergenstal, 2010[72]	RCT, parallel arms NR run in Industry	Start: 2007 End: 2008 1 yrs	US, Canada	485 (667) Source population: not specified but had be under the care of a PI or referring physician to get into study	T1DM, adults, elderly, 7-70 yrs, pregnant women excluded	HbA1c > 9.5%, HbA1c < 7.4%, use of insulin pump within 3 yrs, use of oral hypoglycemic within past 3 mo, not under care of PI or referring physician for at least 6 mo, no access to computer, no history of testing blood glucose on average of 4+ x/day for previous 30 days, intent to become pregnant, history of 2+ severe hypoglycemic events in yr before enrollment
Bin-Abbas, 2006[36]	Non-randomized NR run in Support NR	Start: 2002 End: 2004 12 mo	Saudi Arabia	22 (NR) Source population: Referral clinic	T1DM, pregnant women excluded	Not on conventional insulin therapy (2 injections/day)
Bolli, 2009[45]	RCT, parallel arms Yes run in Industry	Enrollment NR 24 wks	Europe	58 (67) Source population: NR	T1DM, adults, 18-70 yrs	HbA1c ≥ 6.5%, HbA1c ≤ 9.0%, not current pump or MDI user, use of insulin pump ever, fasting plasma glucose <7.0 mmol/L (<126 mg/dl), ever used insulin glargine, BMI > 27, C-peptide > 0.1 nmol/l, >2 severe hypoglycemic episodes in last 6 mo, recent DKA or impaired renal/liver function
Bruttomesso, 2008[46]	RCT, crossover Yes run in Industry	Start: 2003 End: 2005 4 mo	Italy	42 (NR) Source population: 4 Italian centers	T1DM, adults, pregnant women excluded	Use of insulin pump within < 6 mo, unwillingness to measure blood glucose frequently, inability to adjust insulin administration, insulin allergy, untreated retinopathy, cardiovascular disease, hepatic or renal insufficiency, drug abuse, life threatening disease, lactating women, those who intend to become pregnant
Cohen, 2003[41]	RCT, crossover No run in Industry	Enrollment NR 12 mo	Israel	16 (NR) Source population: Referral clinic, Children's medical center	T1DM, pregnant women excluded	Not current pump or MDI user, T1DM diagnosis <2 yrs, C-peptide >0.6ng/ml, chronic disease that could interfere with DM treatment, patients unable to detect hypoglycemia, evidence of microvascular complications or other clinically significant disorders

Table 1. Study design characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Study design Run in period Support	Enrollment dates Followup duration	Location	N enrolled (N Screened) Source population	Included population	Exclusion criteria
Cypryk, 2008[60]	Cohort No run in Other	Start: 2003 End: 2006 36 wks	Poland	116 (NR) Source population: Referral clinic	T1DM, adults, pregnant women only	Male
Deiss, 2006[70]	RCT, parallel arms No run in Industry	Enrollment NR 3 mo	Europe	162 (162) Source population: NR	T1DM, very young, adults	HbA1c > 8.1%
Derosa, 2009[56]	RCT, parallel arms No run in Support NR	Enrollment NR 12 mo	Italy	64 (NR) Source population: University clinic	T1DM & T2DM, adults	Genetic condition affecting lipid metabolism, history of alcohol or drug abuse, neoplastic, infectious or autoimmune disease, poor mental condition, taking other drug able to influence lipid and glycemic metabolism
DeVries, 2002[51]	RCT, parallel arms, Yes run in Industry	Start: 1999 End: 2000 16 wks	the Netherlands	89 (NR) Source population: Referral clinic	T1DM, adults, pregnant women excluded	HbA1c > 8.5%, no contraception used, severe active retinopathy, no impaired hepatic function, no nephropathy, no insulin resistance, no substance abuse, no cardiac disease, no insulin allergy, no past or current psychiatric treatment, not pregnant or breastfeeding
Doyle, 2004[40]	RCT, parallel arms Yes run in Industry, government	Enrollment NR 16 wks	US	32 (NR) Source population: Referral clinic	T1DM, very young, 8-21 yrs, pregnant women excluded	HbA1c > 11%, HbA1c < 6.5%, use of insulin pump ever, medical problem other than treated thyroid or celiac disease, not willing to check blood glucose 4x/day
Garcia-Garcia, 2007[35]	Non-randomized NR run in Government	Enrollment NR	Spain	32 (200) Source population: Pediatric diabetes clinic	T1DM, very young, pregnant women excluded	HbA1c < 7.5%, not current pump or MDI user, T1DM diagnosis after 14 yrs of age, <2 yrs duration and followup in service, daily insulin requirement <0.75 U/kg, previous intensive treatment with <4 glycemic analyses/day, poor parental supervision, poor relationship with care team

Table 1. Study design characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Study design Run in period Support	Enrollment dates Followup duration	Location	N enrolled (N Screened) Source population	Included population	Exclusion criteria
Hanaire-Broutin, 2000[53]	RCT, crossover, Yes run in Industry	Enrollment NR 8 mo	France	41 (NR) Source population: private diabetology practices	T1DM, adults, 21-65 yrs	HbA1c > 10%, not current pump or MDI user, C-peptide positive, untreated retinopathy, impaired renal function, gastric neuropathy, BMI > 30, insulin dose >2U/kg, history of hypoglycemia unawareness, any severe disease that could interfere with the study
Herman, 2005[55]	RCT, parallel arms Yes run in Industry, Government	Enrollment NR 12 mo	NR	107 (144) Source population: NR	T2DM, elderly	HbA1c < 7.0%, BMI > 45 kg/m2, severe impairment of cardiac hepatic or renal function, physical, psychological or cognitive impairments, > 2 episodes of severe hypoglycemia in past yr, hypoglycemia unawareness, age < 60 yrs, absence of T2DM diagnosis for at least one yr
Hieronimus, 2005[62]	Cohort No run in Support NR	Start: 1999 End: 2003	France	56 (NR) Source population: Ob/Gyn clinic	T1DM, adults, pregnant women only	Not current pump or MDI user
Hirsch, 2005[49]	RCT, crossover Yes run in Industry	Enrollment NR 5 wks	US	100 (NR) Source population: NR	T1DM, adults, pregnant women excluded	HbA1c > or = 9.0%, use of insulin pump within at least 3 mo before the screening visit, no contraception used, BMI ≥ 40, impaired hepatic, renal, or cardiac function, hypoglycemia unawareness or recurrent major hypoglycemia, breastfeeding
Hirsch, 2008[69]	RCT, parallel arms Yes run in Industry	Enrollment NR 6 mo	US	146 (138) Source population: NR	T1DM, adults, elderly	HbA1c > 7.5%, use of CGM within 6 mo, < 12 yrs old, > 72 yrs old, diagnosed with diabetes > 1 yr
Hoogma, 2006[48]	RCT, crossover Yes run in Industry	Enrollment NR 6 mo	Europe	272 (NR) Source population: NR	T1DM, adults, 18-65 yrs, pregnant women excluded	No contraception used, hypoglycemia unawareness, progressive retinopathy, renal insufficiency (creatinine ≥ 250 micromol/L), ACS or CVA in last 6 mo, uncontrolled HTN; able to manage intensive insulin therapy, C-peptide secretion, autonomic neuropathy

Table 1. Study design characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Study design Run in period Support	Enrollment dates Followup duration	Location	N enrolled (N Screened) Source population	Included population	Exclusion criteria
JDRF CGM Study Group, 2009[66]	RCT, parallel arms, Yes run in Industry, other	Start: 2007 End: 2008 26 wks	US	129 (NR) Source population: academic, community, and managed case-based practices	T1DM, adults, elderly, 8+ years old	HbA1c > 7.0%, not using a pump or taking < 3 injections/day, had diabetes for < 1 yr
Kernaghan, 2008[61]	Cohort No run in Support NR	Start: 1998 End: 2005 40 weeks	UK	42 (NR) Source population: diabetic pregnancy clinic	T1DM & T2DM, adults, pregnant women only	Male
Kordonouri, 2006[37]	Matched-pair No run in Industry	Enrollment NR 1 years	Germany	104 (665) Source population: Pediatric diabetes clinic	T1DM, very young, pregnant women excluded	Mismatched sex, age difference >1 yr, HbA1C level difference > 0.3%, diabetes duration difference >1 yr
Kordonouri, 2010[64]	RCT, parallel arms No run in period Industry	Start: 2007 End: 2008 52 weeks	Europe	160 (295) Source population: Pediatric Health Center	T1DM, very young, 1-16 yrs	Diagnosis of type 1 diabetes > 4 wks before study entry
Lee, 2007[74]	RCT, parallel arms, No run in Support NR	Enrollment NR 15 wks	US	16 (NR) Source population: Referral clinic	T1DM, adults	HbA1c < 7.5%, not on MDI therapy, exclusion of patients that have used insulin pump
Lepore, 2003[50]	Non-randomized NR run in Support NR	Enrollment NR 1 yrs	Italy	32 (NR) Source population: NR	T1DM, adults	HbA1c < 8.0%, treated with MDI (regular or lispro insulin before each meal plus NPH as basal insulin) for 1+ yr
Minkina-Pedras, 2005[38]	Case-control Yes run in Support NR	Enrollment NR 18 mo	Poland	90 (NR) Source population: children at a diabeteres clinic	T1DM, very young, pregnant women excluded	T2DM, adults, had only ever exclusively used a pump, no continuous care/under care of physician, other metabolic issues (celiac or metabolic problems), if unable to measure insulin dose within 24 hr period

Table 1. Study design characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Study design Run in period Support	Enrollment dates Followup duration	Location	N enrolled (N Screened) Source population	Included population	Exclusion criteria
Nuboer, 2008[32]	RCT, crossover Yes run in period Government, other	Enrollment NR 14 mo	Netherlands	39 (NR) Source population: Referral clinic, Children's hospital	T1DM, very young, pregnant women excluded	HbA1c < 8.0%, random C-peptide >200 pmol, age <4 yrs or >16 yrs, no T1DM diagnosis confirmed, no history of repeated symptomatic hypoglycemia, no attendance of regular school, mental retardation, insufficient Dutch proficiency, chronic complications, pregnancy, co-morbidity, psych problems in child or parent, no home phone
O'Connell, 2009[67]	RCT, parallel arms, No run in Industry	Enrollment NR 3 mo	Australia	62 (77) Source population: Referral clinic	T1DM, adults, 13-40 yrs	HbA1c > 8.5%, use of insulin pump within < 3 mo, diabetes for < 1 yr, patients without internet access, excluded patients that cannot reliably perform SMBG at least 4x/day, unwilling to use subcutaneous sensor component of system for < 70% of study period, Patients with coexistent medical issues that would interfere with their ability to use the system, history of severe hypoglycemia or coexisting illness predisposing to hypoglycemia
Opipari-Arrigan, 2007[33]	RCT, parallel arms NR run in Other	Start: 2002 End: 2003 6 mo	US	18 (NR) Source population: Referral clinic	T1DM, very young, pregnant women excluded	T1DM diagnosis history <1 yr, serious medical conditions, significant developmental delay, known psychiatric illness
Peyrot, 2009[73]	RCT, parallel arms NR run in Industry	Enrollment NR 16 wks	NR	28 (NR) Source population: NR	T1DM, adults	Use of insulin pump ever, optimal glucose control (not specified)
Pozzilli, 2003[43]	RCT, parallel arms No run in Industry, other	Enrollment NR 2 yrs	Italy	23 (NR) Source population: unspecified clinic	T1DM, adults, pregnant women excluded	Diagnosis with age at presentation between 12 and 35 yrs, newly diagnosed, no major contraindications or other major chronic conditions, willing and able to participate in regular followup
Raccah, 2009[65]	RCT, parallel arms No run in Industry	Start: 2006 End: 2007 6 mo	France	132 (148) Source population: Referral clinic, NR	T1DM, very young, adults, 2-65 yrs	HbA1c < 8.0%, diagnosis of diabetes < 12 mo prior to randomization, follow-up by the respective investigator for < 3 mo, not being treated with basal/bolus MDI with rapid insulin analogs at mealtimes

Table 1. Study design characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Study design Run in period Support	Enrollment dates Followup duration	Location	N enrolled (N Screened) Source population	Included population	Exclusion criteria
Radermecker, 2010[63]	RCT, crossover No run in Other	Enrollment NR 12 wks	Europe	13 (NR) Source population: NR	T1DM, adults	Use of insulin pump within < 1 yr, < 6 recorded capillary blood glucose values < 60 mg/dl within the last 14 days, < 4 quarterly visits/ yr to optimize insulin therapy
Raskin, 2003[57]	RCT, parallel arms Yes run in period Industry	Start: 1999 End: 2000 24 wks	US	132 (205) Source population: NR	T2DM, adults, 35+ yrs, pregnant women excluded	HbA1c > 12%, HbA1c < 6.0%, use of insulin pump ever, no contraception used, T2DM for < 2 yrs, treatment for < 5 mo with at least 1 insulin dose per day; with or without OAD, those with impaired hepatic, renal or cardiac function, recurrent major hypoglycemia, BMI> 43, breastfeeding, C-peptide ≤0.2
Rigla, 2008[91]	RCT, crossover No run in Industry, government, other	Enrollment NR 4 mo	Spain	10 (NR) Source population: NR	T1DM, adults	NR
Schiaffini, 2005[39]	Cohort No run in Support NR	Enrollment NR 1 yrs	Italy	36 (NR) Source population: Referral clinic	T1DM, very young, pregnant women excluded	HbA1c < 8.0%, T1DM diagnosis according to ADA guidelines <2 yrs, no change or change in insulin regimen <1 yr before study
Schiaffini, 2007[34]	RCT, parallel arms, No run in Support NR	Enrollment NR 24 mo	Italy	36 (36) Source population: Referral clinic, Children's Hospital	T1DM, very young, pregnant women excluded	HbA1c < 8.0%, age < 9 or > 18 yrs, T1DM diagnosis <3 yrs, T1DM diagnosis not meeting ADA criteria
Skogsberg, 2008[31]	RCT, parallel arms, No run in Industry, government, other	Start: 2001 End: 2004 24 mo	Sweden	72 (NR) Source population: 9 pediatric departments in Sweden	T1DM, very young, pregnant women excluded	NR

Table 1. Study design characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Study design Run in period Support	Enrollment dates Followup duration	Location	N enrolled (N Screened) Source population	Included population	Exclusion criteria
Tamborlane, 2008[68]	RCT, parallel arms Yes run in Other	Start: 2007 26 wks	US	322 (NR) Source population: 10 centers including academic, community, and MCOs	T1DM, adults, elderly, 8+ yrs	HbA1c > 10%, HbA1c < 7.0%, use of CGM within < 6 mo, diabetes diagnosis < 1 yr before randomization, patients not using either an insulin pump or at least three daily insulin injections
Thomas, 2007[47]	RCT, parallel arms NR run in Industry	Enrollment NR 24 wks	NR	21 (NR) Source population: NR	T1DM, adults	No episodes of severe hypoglycemia within preceding 6 mo, C-peptide positive, had used MDI insulin analogue therapy before
Tsui, 2001[52]	RCT, parallel arms Yes run in Industry	Enrollment NR 9 mo	Canada	27 (NR) Source population: Referral clinic	T1DM, adults, 18-60 yrs, pregnant women excluded	Alcohol or drug abuse, in other clinical trial in past 4 wks, diabetic for < 2 yrs, onset of diabetes after 40 yrs old, unable to comply with treatment regimen, >2 severe hypoglycemia episodes in past yr, BMI > 35, severe late complications, CVD, liver disease, cancer
Volpe, 2010[59]	Cohort No run in	Start: 2005 End: 2008 36.4 wks	Italy	42 (NR) Source population: Outpatient clinic	T1DM, adults, pregnant women only	Male
Wainstein, 2005[58]	RCT, crossover Yes run in Support NR	Enrollment NR 18 wks	NR	40 (58) Source population: diabetic centers	T2DM, adults, elderly	HbA1c < 8.5%, BMI < 30kg/m2 or > 45 kg/m2, age < 30 and > 70 yrs, diet treatment < 3 mo, metformin dose < 850 mg 2 to 3 x/day, new-onset diabetes (< 6 mo), T1DM, diabetes secondary to pancreatitis, history of CAD or CVA in last 12 mo, pre-proliferative and proliferative diabetic retinopathy, advanced nephropathy (Creatinine > 1.5 mg/dl, liver enzymes> 2 times upper limit, HbA1C >15 %
Weintrob, 2003[42]	RCT, crossover Yes run in Industry	Enrollment NR 3.5 mo	Israel	23 (24) Source population: National Institute for Childhood Diabetes of Schneider Children's Medical Center	T1DM, 8-14 yrs	Patients with sufficient C-peptide secretion (>=200 pmol/L), patients unable to cope with treatment procedures

Table 1. Study design characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Study design Run in period Support	Enrollment dates Followup duration	Location	N enrolled (N Screened) Source population	Included population	Exclusion criteria
Yoo, 2008[92]	RCT, parallel arms No run in Industry, government, other	Start: 2007 End: 2007 3 mo	Korea	65 (65) Source population: NR	T2DM, adults, elderly, 20-80 yrs	HbA1c > 10%, HbA1c < 8.0%, use of oral hypoglycemic within < 1 yr, stable insulin or OHA regimen for < 2 mo, stable dose of antihypertensive or lipid-lowering drugs for < 4 wks, severe diabetic complications (e.g. retinopathy), steroid use in previous 3 mo, liver/kidney disease, other medical problems that affected study results or trial participation

Abbreviations: ACS = acute coronary syndrome; ADA = American Diabetes Association; BMI = body mass index; CVA = cerebrovascular accident, stroke; CVD = cardiovascular disease; DKA = diabetic ketoacidosis; DM = diabetes mellitus; hr = hour; kg = kilogram; L = liter; m = meter; MCO = managed care organization; MDI = multiple daily injections; ml = milliliter; mmol = micromoles; mo = month(s); ng = nanograms; NR= not reported; OAD = oral anti diabetic; OHA = oral hypoglycemic agents; pmol = picomole; psych = psychological; RCT = randomized controlled trial; SMBG = self monitoring of blood glucose; T1DM = Type 1 Diabetes Mellitus; T2DM = Type 2 Diabetes Mellitus; U = units; wks = weeks; x/day = times per day; yrs = years

Table 2. Study population characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Inter-vention, n	Age (years) Male (%)	Race (%)	Baseline HbA1c (%)	Baseline weight (kg)/BMI (kg/m2)	Duration of diabetes (years)	Insulin delivery device (%)	With-drawals (N)
Beck, 2010[71]	SMBG	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	NR
Beck, 2010[71]	rtCGM	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	NR
Bergenstal, 2010[72]	MDI + SMBG, 241	Age NR 56	C: 92 His: 3 Other: 5	Mean: 8.3	Mean BMI: 25.6, Mean weight: 73	Mean: 15.4	MDI:100	22
Bergenstal, 2010[72]	CSII + rtCGM, 244	Age NR 57	C: 91 His: 3 Other: 7	Mean: 8.3	Mean BMI: 25.3, Mean weight: 71.9	Mean: 15.2	CSII:100	20
Bin-Abbas, 2006[36]	MDI, 8	Mean: 9, Range: 7-12 62.5	NR	Mean: 10.1	BMI/Weight NR	Mean: 6	NA	NR
Bin-Abbas, 2006[36]	CSII, 14	Mean: 12.8, Range: 4-16 50	NR	Mean: 10.2	BMI/Weight NR	Mean: 6	NA	NR
Bin-Abbas, 2006[36]	MDI, 8	Mean: 9, Range: 7-12 62.5	NR	Mean: 10.1	BMI/Weight NR	Mean: 6	NA	NR
Bolli, 2009[45]	MDI, 26	Mean: 21.5 54	NR	Mean: 7.8	Mean BMI: 24.3, Mean weight: 70.8	Mean: 20.9	NA	NR
Bolli, 2009[45]	CSII, 24	Mean: 19.1 54	NR	Mean: 7.7	Mean BMI: 23.8, Mean weight: 70.1	Mean: 18.5	NA	NR
Bruttomesso, 2008[46]	MDI, 15	Age NR 47	NR	Mean: 7.4	Mean BMI: 22.9, Mean weight: 66.8	Mean: 15.7	NA	NR
Bruttomesso, 2008[46]	CSII, 24	Age NR 50	NR	Mean: 7.6	Mean BMI: 24.1, Mean weight: 71	Mean: 17.2	NA	NR
Cohen, 2003[41]	MDI, 16	Median: 14.2 37.5	NR	Mean: 8.48	BMI/Weight NR	Duration NR	NA	3
Cohen, 2003[41]	CSII, 16	Median: 14.2 37.5	NR	Mean: 8.58	BMI/Weight NR	Duration NR	NA	1
Cypryk, 2008[60]	MDI, 86	Age NR 0	C: 100	HbA1c NR	Mean BMI: 23.7	Mean: 7.7	NA	NR
Cypryk, 2008[60]	CSII, 30	Age NR 0	C: 100	HbA1c NR	Mean BMI: 23.5	Mean: 12.7	NA	NR
Deiss, 2006[70]	SMBG	Age NR	NR	Mean: 9.7	BMI/Weight NR	Duration NR	NA	0
Deiss, 2006[70]	rtCGM	Age NR	NR	Mean: 9.5	BMI/Weight NR	Duration NR	NA	4
Deiss, 2006[70]	rtCGM	Age NR	NR	Mean: 9.6	BMI/Weight NR	Duration NR	NA	1

Table 2. Study population characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Inter-vention, n	Age (years) Male (%)	Race (%)	Baseline HbA1c (%)	Baseline weight (kg)/BMI (kg/m2)	Duration of diabetes (years)	Insulin delivery device (%)	With-drawals (N)
Derosa, 2009[56]	MDI, 32	Age NR 50	NR	Mean: 9.3	Mean BMI: 29.8	Duration NR	NA	NR
Derosa, 2009[56]	CSII, 32	Age NR 47	NR	Mean: 9.2	Mean BMI: 29.5	Duration NR	NA	NR
DeVries, 2002[51]	MDI, 40	Age NR 53	NR	Mean: 9.3	Mean weight: 79.8	Mean: 18	NA	0
DeVries, 2002[51]	CSII, 39	Age NR 54	NR	Mean: 9.3	Mean weight: 77.3	Mean: 17.6	NA	7
Doyle, 2004[40]	MDI, 16	Age NR 50	C: 81 AA: 6 His: 12	Mean: 8.2	BMI/Weight NR	Mean: 5.6	NA	1
Doyle, 2004[40]	CSII, 16	Age NR 38	C: 69 AA: 12 His: 19	Mean: 8.1	BMI/Weight NR	Mean: 6.8	NA	0
Garcia-Garcia, 2007[35]	MDI, 24	Mean: 12.8 41.7	NR	Mean: 7.8	BMI/Weight NR	Mean: 5.7	NA	NR
Garcia-Garcia, 2007[35]	CSII, 8	Mean: 11.6 37.5	NR	Mean: 7.6	BMI/Weight NR	Mean: 5.7	NA	NR
Hanaire-Broutin, 2000[53]	MDI + rtCGM, 41	Age NR 51	NR	Mean: 8.39	Mean BMI: 24, Mean weight: 68.2	Mean: 20	NA	1
Hanaire-Broutin, 2000[53]	CSII + SMBG	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	NR
Herman, 2005[55]	MDI, 54	Age NR 44	C: 91 AA: 4 His: 4 Other: 2	Mean: 8.1	Mean BMI: 31.8	Mean: 15.4	NA	4
Herman, 2005[55]	CSII, 53	Age NR 72	C: 81 AA: 8 His: 8 Other: 4	Mean: 8.4	Mean BMI: 32.5	Mean: 16.9	NA	5
Hieronimus, 2005[62]	MDI, 23	Mean: 26 0	NR	Mean: 7.6	Mean BMI: 21.8	Mean: 9.8	NA	NR
Hieronimus, 2005[62]	CSII, 33	Mean: 30 0	NR	Mean: 7.5	Mean BMI: 23.8	Mean: 13.9	NA	NR
Hirsch, 2005[49]	MDI	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	NR
Hirsch, 2005[49]	CSII	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	NR

Table 2. Study population characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Inter-vention, n	Age (years) Male (%)	Race (%)	Baseline HbA1c (%)	Baseline weight (kg)/BMI (kg/m2)	Duration of diabetes (years)	Insulin delivery device (%)	With-drawals (N)
Hirsch, 2008[69]	SMBG, 72	Mean: 33.2, Median: 34, Range: 12-72 39	C: 90 AA: 1 Asian: 3 His: 6	Mean: 8.39, Median: 34, Range: 7.5-10.6	Mean BMI: 26.3, Median BMI: 25.9, Mean weight: 75.4, Median weight: 72.4	Mean: 16.7 Median: 13	CSII:100	2
Hirsch, 2008[69]	rtCGM, 66	Mean: 33, Median: 34.5, Range: 12-64 48	C: 89 AA: 2 Asian: 0 His: 9	Mean: 8.49, Median: 34.5, Range: 7.5-10.7	Mean BMI: 26.9, Median BMI: 25.9, Mean weight: 76.8, Median weight: 74	Mean: 20.8, Median: 20.5	CSII:100	6
Hoogma, 2006[48]	MDI, 129	Age NR 47	NR	Mean: 8.3	Mean BMI: 24.8	Mean: 15.4	NA	NR
Hoogma, 2006[48]	CSII, 127	Age NR 48	NR	Mean: 8.2	Mean BMI: 24.9	Mean: 14.4	NA	NR
JDRF CGM Study Group, 2009[66]	SMBG, 62	Mean: 32 48	C: 94	Mean: 6.5	BMI/Weight NR	Duration NR	CSII:79 MDI:21	2
JDRF CGM Study Group, 2009[66]	rtCGM, 67	Mean: 29.3 46	C: 94	Mean: 6.4	BMI/Weight NR	Duration NR	CSII:93 MDI:7	0
Kernaghan, 2008[61]	MDI, 18	Age NR 0	NR	Mean: 8.01	BMI/Weight NR	Duration NR	NA	NR
Kernaghan, 2008[61]	CSII, 24	Age NR 0	NR	Mean: 7.62	BMI/Weight NR	Duration NR	NA	NR
Kordonouri, 2006[37]	MDI, 52	Mean: 6.72 40.4	NR	Mean: 8.17	BMI/Weight NR	Mean: 4.83	NA	NR
Kordonouri, 2006[37]	CSII, 52	Mean: 6.72 40.4	NR	Mean: 8.17	BMI/Weight NR	Mean: 4.83	NA	NR
Kordonouri, 2010[64]	CSII + SMBG, 80	Mean: 9.1 50	NR	Mean: 11.5	BMI/Weight NR	Duration NR	CSII:100	2
Kordonouri, 2010[64]	CSII + rtCGM, 80	Mean: 8.5 50	NR	Mean: 11.2	BMI/Weight NR	Duration NR	CSII:100	4
Lee, 2007[74]	SMBG, 8	Age NR	NR	Mean: 8.58	BMI/Weight NR	Duration NR	MDI:100	NR
Lee, 2007[74]	rtCGM, 8	Age NR	NR	Mean: 9.45	BMI/Weight NR	Duration NR	CSII:100	NR
Lepore, 2003[50]	MDI, 16	Age NR 44	NR	HbA1c NR	BMI/Weight NR	Mean: 14.7	NA	NR
Lepore, 2003[50]	CSII, 16	Age NR 50	NR	HbA1c NR	BMI/Weight NR	Mean: 19.6	NA	NR

Table 2. Study population characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Inter-vention, n	Age (years) Male (%)	Race (%)	Baseline HbA1c (%)	Baseline weight (kg)/BMI (kg/m2)	Duration of diabetes (years)	Insulin delivery device (%)	With-drawals (N)
Minkina-Pedras, 2005[38]	MDI, 25	Mean: 7 48	C: 100	Mean: 7	BMI/Weight NR	Mean: 2.9	NA	0
Minkina-Pedras, 2005[38]	CSII, 30	Mean: 6.7 33	C: 100	Mean: 7.1	BMI/Weight NR	Mean: 2.7	NA	1
Minkina-Pedras, 2005[38]	CSII, 35	Mean: 13.9 51	C: 100	Mean: 7.4	BMI/Weight NR	Mean: 3.1	NA	0
Nuboer, 2008[32]	MDI + SMBG, 19	Mean: 10 52.6	C: 90	Mean: 7.98	BMI/Weight NR	Mean: 4.7	NA	NR
Nuboer, 2008[32]	CSII + SMBG, 20	Mean: 10 35	C: 90	Mean: 7.66	BMI/Weight NR	Mean: 5.6	NA	1
O'Connell, 2009[67]	SMBG, 31	Age NR 29	NR	Mean: 7.5	BMI/Weight NR	Mean: 9.2	CSII:100	2
O'Connell, 2009[67]	rtCGM, 31	Age NR 29	NR	Mean: 7.3	BMI/Weight NR	Mean: 11.1	CSII:100	5
Opipari-Arrigan, 2007[33]	MDI + rtCGM, 9	Mean: 4.4 50	C: 100	Mean: 7.98	Mean BMI: 15.9	Duration NR	NA	1
Opipari-Arrigan, 2007[33]	CSII + rtCGM, 9	Mean: 4.4 62.5	C: 100	Mean: 8.26	Mean BMI: 17	Duration NR	NA	3
Peyrot, 2009[73]	MDI + SMBG, 14	Age NR	NR	Mean: 8.32	Mean weight: 82.6	Duration NR	CSII:0	1
Peyrot, 2009[73]	CSII + rtCGM, 14	Age NR	NR	Mean: 8.87	Mean weight: 77.7	Duration NR	CSII:0	0
Pozzilli, 2003[43]	MDI, 12	Mean: 18.9	NR	Mean: 10.3	Mean BMI: 20.9	Mean: 0	NA	4
Pozzilli, 2003[43]	CSII, 7	Mean: 17.9	NR	Mean: 11.7	Mean BMI: 19.8	Mean: 0	NA	0
Raccah, 2009[65]	CSII + SMBG, 60	Age NR 57	NR	Mean: 9.28	Mean BMI: 22.5, Mean weight: 62.6	Mean: 12.3	CSII:100	6
Raccah, 2009[65]	rtCGM, 55	Age NR 55	NR	Mean: 9.11	Mean BMI: 23.5, Mean weight: 65.7	Mean: 11.2	CSII:100	14
Radermecker, 2010[63]	CSII + SMBG, 13	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	1
Radermecker, 2010[63]	rtCGM, 13	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	3
Raskin, 2003[57]	MDI, 61	Age NR 57	C: 82 AA: 13 Other: 5	Mean: 8	Mean BMI: 32.2	Mean: 11.9	NA	6
Raskin, 2003[57]	CSII, 66	Age NR 64	C: 80 AA: 12 Other: 8	Mean: 8.2	Mean BMI: 32.2	Mean: 13.8	NA	6

Table 2. Study population characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Inter-vention, n	Age (years) Male (%)	Race (%)	Baseline HbA1c (%)	Baseline weight (kg)/BMI (kg/m2)	Duration of diabetes (years)	Insulin delivery device (%)	With-drawals (N)
Rigla, 2008[91]	SMBG, 10	Mean: 41.2	NR	HbA1c NR	BMI/Weight NR	Mean: 14.9	CSII:100	0
Rigla, 2008[91]	rtCGM, 10	Mean: 41.2	NR	HbA1c NR	BMI/Weight NR	Mean: 14.9	CSII:100	0
Schiaffini, 2005[39]	MDI, 16	Mean: 10.7 31.3	NR	Mean: 8.9	BMI/Weight NR	Mean: 5.5	NA	NR
Schiaffini, 2005[39]	CSII, 20	Mean: 12.7 25	NR	Mean: 8.5	BMI/Weight NR	Mean: 5.5	NA	NR
Schiaffini, 2007[34]	MDI, 17	Mean: 12.9 47.1	NR	Mean: 8.5	BMI/Weight NR	Mean: 5.7	NA	NR
Schiaffini, 2007[34]	CSII, 19	Mean: 12.5 52.6	NR	Mean: 8.3	BMI/Weight NR	Mean: 5.8	NA	NR
Skogsberg, 2008[31]	MDI, 38	Mean: 12.3 58.3	NR	Mean: 8.4	BMI/Weight NR	Duration NR	NA	5
Skogsberg, 2008[31]	CSII, 34	Mean: 11.8 58.3	NR	Mean: 8.2	BMI/Weight NR	Duration NR	NA	NR
Tamborlane, 2008[68] Age strata:8-14	SMBG, 58	Mean: 11.6 50	C: 93	Mean: 8	BMI/Weight NR	Mean: 5.3	CSII:84 MDI:16	0
Tamborlane, 2008[68] Age strata:>25	SMBG, 46	Mean: 44.6 43	C: 89	Mean: 7.6	BMI/Weight NR	Mean: 21.8	CSII:85 MDI:15	0
Tamborlane, 2008[68] Age strata:15-24	SMBG, 53	Mean: 18.2 34	C: 96	Mean: 7.9	BMI/Weight NR	Mean: 8.8	CSII:75 MDI:25	2
Tamborlane, 2008[68] Age strata:>25	rtCGM, 52	Mean: 41.2 40	C: 100	Mean: 7.6	BMI/Weight NR	Mean: 23.6	CSII:83 MDI:17	2
Tamborlane, 2008[68] Age strata:8-14	rtCGM, 56	Mean: 11.4 52	C: 91	Mean: 7.9	BMI/Weight NR	Mean: 6.2	CSII:84 MDI:16	0
Tamborlane, 2008[68] Age strata:15-24	rtCGM, 57	Mean: 18.8 49	C: 82	Mean: 8	BMI/Weight NR	Mean: 9.5	CSII:67 MDI:33	1
Thomas, 2007[47]	MDI, 7	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	NR
Thomas, 2007[47]	CSII, 7	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	NR
Tsui, 2001[52]	MDI, 14	Age NR 71	NR	Mean: 8.16	Mean BMI: 26, Median BMI: 27	Mean: 15, Median: 13	NA	0
Tsui, 2001[52]	CSII, 13	Age NR 62	NR	Mean: 7.73	Mean BMI: 27, Median BMI: 27	Mean: 17, Median: 13	NA	1
Volpe, 2010[59]	MDI, 22	Age NR 0	C: 100	HbA1c NR	Mean BMI: 23.7	Mean: 12.1	NA	NR
Volpe, 2010[59]	CSII + SMBG, 20	Age NR 0	C: 100	HbA1c NR	Mean BMI: 23	Mean: 16	NA	NR

Table 2. Study population characteristics of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Inter-vention, n	Age (years) Male (%)	Race (%)	Baseline HbA1c (%)	Baseline weight (kg)/BMI (kg/m2)	Duration of diabetes (years)	Insulin delivery device (%)	With-drawals (N)
Wainstein, 2005[58]	MDI, 20	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	6
Wainstein, 2005[58]	CSII, 20	Age NR	NR	HbA1c NR	BMI/Weight NR	Duration NR	NA	5
Weintrob, 2003[42]	MDI, 12	Mean: 11.6 50	NR	Mean: 8.6	BMI/Weight NR	Mean: 6.3	NA	0
Weintrob, 2003[42]	CSII, 11	Mean: 11.9 36	NR	Mean: 7.9	BMI/Weight NR	Mean: 5.3	NA	0
Yoo, 2008[92]	SMBG, 28	Mean: 57.5 50	NR	Mean: 8.7	Mean BMI: 25.7, Mean weight: 65.7	Mean: 13.3	NA	5
Yoo, 2008[92]	rtCGM, 29	Mean: 54.6 34	NR	Mean: 9.1	Mean BMI: 25, Mean weight: 63.3	Mean: 11.7	NA	3

Abbreviations: AA = African American; BMI = body mass index; C = Caucasian; CSII = continuous subcutaneous insulin infusion; His = Hispanic; kg = kilogram; NA = not applicable; NR = not reported; rtCGM = real time continuous glucose monitoring; SMBG = self monitoring of blood glucose

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Beck, 2010[71]	MDI	NA	SMBG Monitor use: 4+	NA	26 wks	Titration guidelines NR Targets NR	NA
Beck, 2010[71]	CSII	NA	rtCGM model unspec.	NA	26 wks	Titration guidelines NR Targets NR	NA
Bergenstal, 2010[72]	MDI	MDI Injections NR Short acting: aspart Long acting: glargine	SMBG Monitor use: NA Fingerstick: NR	NA	1 yr	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Bergenstal, 2010[72]	CSII	MM REAL Short acting: aspart	MM paradigm Monitor use: unclear if just used for 1 wk at baseline, 6 mo, and 12 mo Fingerstick: NR	Yes	1 yr	Titration guidelines NR Between visit guidelines NR Targets NR	NR
Bin-Abbas, 2006[36]	MDI	MDI 4+ times/day Short acting: lispro Long acting: glargine	NA	NA	6 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Bin-Abbas, 2006[36]	MDI	MDI 4+ times/day Short acting: lispro Long acting: glargine	NA	NA	6 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Bin-Abbas, 2006[36]	CSII	Minimed unspec. Short acting: lispro	NA	NR	12 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Bolli, 2009[45]	MDI	MDI 4+ times/day Short acting: lispro Long acting: glargine	NA	NA	24 wks	Titration guidelines: Yes Between visit guidelines NR Preprandial: 90-140 mg 5.0-7.7 mmol, FG: 80-120 mg, 4.4-6.6 mmol, 2 hr postprandial: <7.7 mmol, other target: bedtime blood glucose 110-150 mg, 1-8.3 mmol	NA
Bolli, 2009[45]	CSII	MM 508, Short acting: lispro	NA	NR	24 wks	Titration guidelines: Yes Between visit guidelines NR Preprandial: 90-140 mg 5.0-7.7 mmol, FG: 80-120 mg, 4.4-6.6 mmol, 2 hr postprandial: <7.7 mmol, other target: bedtime blood glucose 110-150 mg, 6.1-8.3 mmol,	NA
Bruttomesso, 2008[46]	MDI	MDI 4+ times/day Short acting: lispro Long acting: glargine	NA	NA	4 mo	Titration guidelines NR Between visit guidelines NR Preprandial: 5.0-6.7 mmol, FG: 5.0-6.7 mmol, 2 hr postprandial: 6.0-8.5 mmol (90 min after meals), other target: 6.1-7.5 mmol/l at bedtime	NA
Bruttomesso, 2008[46]	CSII	DR DTRON, Animas, DR HTron v100, MM 508 Short acting: lispro	NA	NR	4 mo	Titration guidelines NR Between visit guidelines NR Preprandial: 5.0-6.7 mmol, FG: 5.0-6.7 mmol, 2 hr postprandial: 6.0-8.5 mmol (90 min after meals), other target: 6.1-7.5 mmol at bedtime	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Cohen, 2003[41]	MDI	MDI 4+ times/day Short acting: Reg insulin Long acting: NPH	NA	NA	12 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Cohen, 2003[41]	CSII	Tayco Disetronic Short acting: lispro	NA	NR	12 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Cypryk, 2008[60]	MDI	MDI Injections NR Short acting: 30% used insulin lispro and 70% used regular insulin Long acting: NPH	NA	NA	36 wks	Titration guidelines NR Between visit guidelines NR Preprandial: 3.3-5.0 mmol, FG: 3.3-5.0 mmol, 2 hr postprandial: <6.7 mmol	NA
Cypryk, 2008[60]	CSII	MM 507c, MM 508, Short acting: 90% used insulin lispro; 10% not reported	NA	Yes	36 wks	Titration guidelines NR Between visit guidelines NR Preprandial: 3.3-5.0 mmol, FG: 3.3-5.0 mmol, 2 hr postprandial: <6.7 mmol,	NA
Deiss, 2006[70]	NA	NA	SMBG Monitor use: NA Fingerstick: NR	NA	3 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Deiss, 2006[70]	NA	NA	MM guardian rtCGM Monitor use: continuously Fingerstick: NR	NA	3 mo	Titration guidelines NR Between visit guidelines NR Targets NR	Hyperglycemia: 170-250 mg/dL Hypoglycemia: 50-80 mg/dL

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Deiss, 2006[70]	NA	NA	MM guardian rtCGM Monitor use: biweekly for 3 day periods every 2 wks Fingerstick: NR	NA	3 mo	Titration guidelines NR Between visit guidelines NR Targets NR	Hyperglycemia: 170-250 mg/dL Hypoglycemia: 50-80 mg/dL
Derosa, 2009[56]	MDI	MDI 4+ times/day Short acting: lispro Long acting: glargine	NA	NA	1 yr	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Derosa, 2009[56]	CSII	pump unspec., Short acting: lispro	NA	NR	1 yr	Titration guidelines NR Between visit guidelines NR Targets NR	NA
DeVries, 2002[51]	MDI	MDI 4+ times/day Short acting: aspart Long acting: NPH	NA	NA	16 wks	Titration guidelines: Yes Between visit guidelines: Yes Preprandial: 5.0-7.0 mmol, other target: 90-min PPG: 5-9; bedtime glucose: 7-10 mmol/L	NA
DeVries, 2002[51]	CSII	Disetronic H-TRONplus Short acting: aspart Long acting: no long acting	NA	Yes	16 wks	Titration guidelines: Yes Between visit guidelines: Yes Preprandial: 5.0-7.0 mmol, other target: 90-min PPG: 5-9; bedtime glucose: 7-10 mmol/L	NA
Doyle, 2004[40]	MDI	MDI 4+ times/day Short acting: aspart Long acting: glargine	NA	NA	16 wks	Titration guidelines: Yes Between visit guidelines: Yes Target HbA1c: 7, preprandial: 70-120 mg, other target: 90-150mg pre bedtime	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Doyle, 2004[40]	CSII	MM 508, MM Paradigm 511 Short acting: aspart	NA	Yes	16 wks	Titration guidelines: Yes Between visit guidelines: Yes Target HbA1c: 7, preprandial: 70-120 mg, other target: 90-150mg pre bedtime	NA
Garcia-Garcia, 2007[35]	MDI	MDI 3 times/day Short acting: lispro Long acting: glargine	NA	NA	24 mo	Titration guidelines: Yes Between visit guidelines NR Preprandial: 70-140 mg	NA
Garcia-Garcia, 2007[35]	CSII	DR HTron v100 Short acting: lispro	NA	NR	24 mo	Titration guidelines: Yes Between visit guidelines NR Preprandial: 70-140 mg	NA
Hanaire-Broutin, 2000[53]	MDI	MDI 4+ times/day Short acting: lispro Long acting: NPH	Ayer Glucomatic Esprit memory meter Monitor use: before and 2 hr after each meal	NA	4 mo	Titration guidelines: Yes Between visit guidelines: Yes Preprandial: 70-120 mg, FG: 70-120 mg	NA
Hanaire-Broutin, 2000[53]	CSII	MM 506, MM 507c, Disetronic HTron D or V Short acting: lispro	SMBG Monitor use: before and 2 hr after each meal	NR	4 mo	Titration guidelines: Yes Between visit guidelines: Yes Preprandial: 70-120 mg, FG: 70-120 mg	NA
Herman, 2005[55]	MDI	MDI 4+ times/day Short acting: lispro Long acting: glargine	NA	NA	12 mo	Titration guidelines: Yes Between visit guidelines: Yes Target HbA1c: 5.6, preprandial: 80 - 120 mg, other target: 100 - 150 at bed time	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Herman, 2005[55]	CSII	MM 508 Short acting: lispro	NA	NR	12 mo	Titration guidelines: Yes Between visit guidelines: Yes Target HbA1c: 5.6, preprandial: 80 - 120 mg, other target: 100 - 150 at bed time,	NA
Hieronimus, 2005[62]	MDI	MDI 4+ times/day	NA	NA	NR	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Hieronimus, 2005[62]	CSII	pump unspec.	NA	Yes	NR	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Hirsch, 2005[49]	MDI	MDI 4+ times/day Short acting: aspart Long acting: glargine	NA	NA	5 wks	Titration guidelines: No Between visit guidelines NR FG: 90-126 mg, target: predinner glucose 90-126 mg	NA
Hirsch, 2005[49]	CSII	pump unspec. Short acting: aspart	NA	No	5 wks	Titration guidelines: No Between visit guidelines NR FG: 90-126 mg, target: predinner glucose 90-126 mg,	NA
Hirsch, 2008[69]	NA	NA	SMBG Monitor use: NA Fingerstick: NR	NA	6 mo	Titration guidelines NR Between visit guidelines NR Target HbA1c: 7.5	NA
Hirsch, 2008[69]	NA	NA	MM paradigm Monitor use: Not reported Fingerstick: NR	NA	6 mo	Titration guidelines NR Between visit guidelines NR Targets NR	Hyperglycemia: 180 mg/dL Hypoglycemia: 70 mg/dL

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Hoogma, 2006[48]	MDI	MDI 4+ times/day at least 3 preprandial and 1 NPH Short acting: lispro Long acting: NPH	NA	NA	6 mo	Titration guidelines NR Between visit guidelines: Yes Preprandial: 4.0-7.0 mmol, FG: 4.0-7.0 mmol, other target: bedtime 6-10 mmol/L, 1hr postprandial 8-10 mmol/L	NA
Hoogma, 2006[48]	CSII	DR HTron v100, Disetronic H-TRONplus V100 Short acting: lispro	NA	Yes	6 mo	Titration guidelines NR Between visit guidelines: Yes Preprandial: 4.0-7.0 mmol, FG: 4.0-7.0 mmol, other target: bedtime 6-10 mmol/L, 1hr postprandial 8-10 mmol/L	NA
JDRF CGM Study Group, 2009[66]	NA	NA	SMBG Monitor use: NA Fingerstick: 4+ times/day	NA	26 wks	Titration guidelines NR Between visit guidelines NR Targets NR	NA
JDRF CGM Study Group, 2009[66]	NA	NA	Abbott freestyle navigator, MM paradigm, Dexcom sts, Monitor use: daily	NA	26 wks	Titration guidelines NR Between visit guidelines NR Targets NR	NR
Kernaghan, 2008[61]	MDI	MDI 4+ times/day Short acting: short-acting or rapid-acting insulin Long acting: unspecified	NA	NA	40 wks	Titration guidelines NR Between visit guidelines: Yes Target HbA1c: 6.5, FG: 4-5.5 mmol, other target: 1-hr PPG between 4-7 mmol/L	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Kernaghan, 2008[61]	CSII	DR DTRON, Disetronic/Roche H-Tron, Medtronic Paradigm 508 Short acting: lispro Long acting: no long acting	NA	NR	37 wks	Titration guidelines NR Between visit guidelines: Yes Target HbA1c: 6.5, FG: 4-5.5 mmol, other target: 1-hr PPG between 4-7 mmol/L	NA
Kordonouri, 2006[37]	MDI	MDI 3.5 Short acting: NR Long acting: NPH	NA	NA	1 yr	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Kordonouri, 2006[37]	CSII	pump unspec., Short acting: NR	NA	NR	1 yr	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Kordonouri, 2010[64]	NA	Minimed paradigm 515/715 Short acting: NR	SMBG Monitor use: NA Fingerstick: 4+ times/day	NR	52 wks	Titration guidelines NR Between visit guidelines NR Preprandial: 5.0-8.0 mmol, 2 hr postprandial: <10.0 mmol, Other target: 6.7-10.0 mmol,	NA
Kordonouri, 2010[64]	NA	MM REAL Short acting: NR	MM Paradigm Monitor use: daily Fingerstick: NR	NR	52 wks	Titration guidelines NR Between visit guidelines NR Preprandial: 5.0-8.0 mmol, 2 hr postprandial: <10.0 mmol	NR
Lee, 2007[74]	NA	NA	SMBG Monitor use: NA Fingerstick: NR	NA	15 wks	Titration guidelines NR Between visit guidelines NR Other target: 90-120 mg/dL (7am-10pm), 100-120 mg/dL (10pm-7am)	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Lee, 2007[74]	NA	NA	MM paradigm Monitor use: At least 5 days every wk (for a max of 72 hrs at a time) Fingerstick: 4+ times/day	NA	15 wks	Titration guidelines: Yes Between visit guidelines NR Other target: 90-120 mg/dL (7am-10pm), 100-120 mg/dL (10pm-7am)	Hyperglycemia: 200 mg/dL Hypoglycemia: 80 mg/dL
Lepore, 2003[50]	MDI	MDI 4+ times/day Short acting: lispro Long acting: glargine	NA	NR	1 yr	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Lepore, 2003[50]	CSII	pump unspec. Short acting: lispro	NA	NR	1 yr	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Minkina-Pedras, 2005[38]	MDI	MDI Injections NR Short acting: lispro	NA	NA	18 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Minkina-Pedras, 2005[38]	CSII	MM 508 Short acting: lispro	NA	No	18 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Minkina-Pedras, 2005[38]	CSII	DR HTron v100, DR DTRON Short acting: lispro	NA	No	18 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Nuboer, 2008[32]	MDI	MDI 3 times/day Short acting: aspart	SMBG Monitor use: NA Fingerstick: 4+ times/day	NA	14 mo	Titration guidelines: Yes Between visit guidelines: Yes Other target: 4.0-10.0 mmol/L,	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Nuboer, 2008[32]	CSII	DR HTron v100, Short acting: aspart	SMBG Monitor use: NA Fingerstick: 4+ times/day	NR	14 mo	Titration guidelines: Yes Between visit guidelines: Yes Other target: 4.0-10.0 mmol/L,	NA
O'Connell, 2009[67]	NA	NA	SMBG Monitor use: NA Fingerstick: 4+ times/day	NA	3 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
O'Connell, 2009[67]	NA	NA	MM paradigm Monitor use: >70% of 3-month study period Fingerstick: 4+ times/day	NA	3 mo	Titration guidelines NR Between visit guidelines NR Targets NR	Hyperglycemia: 12 mmol/dL Hypoglycemia: 4.5 mmol/L
Opipari-Arrigan, 2007[33]	MDI	MDI 3 times/day Short acting: lispro Long acting: NPH	Medtronic MiniMed CGMS Monitor use: Median time for sensor wear was 48 hours with glucose recordings every 5 min Fingerstick: NR	NA	6 mo	Titration guidelines: Yes Between visit guidelines NR Targets NR	Hyperglycemia: >180 mg/dL Hypoglycemia: <70 mg/dL
Opipari-Arrigan, 2007[33]	CSII	Animas infusion pump Short acting: lispro Long acting: NPH	Medtronic MiniMed CGMS Monitor use: Median time for sensor wear was 48 hours with glucose recordings every 5 min Fingerstick: NR	Yes	6 mo	Titration guidelines: Yes Between visit guidelines NR Targets NR	Hyperglycemia: >180 mg/dL Hypoglycemia: <70 mg/dL
Peyrot, 2009[73]	MDI	MDI, Injections NR Short acting: rapid acting analogs (unspecified) Long acting: glargine	SMBG Monitor use: NA Fingerstick: NR	NA	16 wks	Titration guidelines NR Between visit guidelines NR Targets NR	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Peyrot, 2009[73]	CSII	MM paradigm 722	SMBG, RT-CGM using integrated pump/monitor Monitor use: not specified Fingerstick: NR	Yes	16 wks	Titration guidelines: No Between visit guidelines: No Targets NR	NR
Pozzilli, 2003[43]	MDI	MDI 4+ times/day Short acting: unspecified Long acting: NPH	NA	NA	2 yrs	Titration guidelines: Yes Between visit guidelines: Yes Targets NR	NA
Pozzilli, 2003[43]	CSII	MM 507c Short acting: lispro Long acting: no long acting	NA	Yes	2 yrs	Titration guidelines NR Between visit guidelines NR Preprandial: 3.9-8.3 mmol for those with no history of hypoglycemia; 4.4-8.9 mmol for those with reduced hypoglycemia awareness; and higher targets for those with recurrent severe hypoglycemia	NA
Raccah, 2009[65]	NA	MM paradigm 512 Short acting: NR	SMBG Monitor use: NA Fingerstick: ≥ 3 times/day	NA	6 mo	Titration guidelines: Yes Between visit guidelines: Yes Targets NR	NA
Raccah, 2009[65]	NA	NA	MM paradigm, Monitor use: 70% of the time Fingerstick: ≥ 3 times/day	NA	6 mo	Titration guidelines: Yes Between visit guidelines: Yes Targets NR	NR
Radermecker, 2010[63]	NA	pump unspec. Short acting: NR	SMBG Monitor use: NA Fingerstick: NR	NA	12 wks	Titration guidelines NR Between visit guidelines NR Targets NR	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Radermecker, 2010[63]	NA	NA	MM Guardian rtCGM Monitor use: patients were offered to use it permanently Fingerstick: Other	NA	12 wks	Titration guidelines NR Between visit guidelines NR Targets NR	Hyperglycemia: 240 mg/dL Hypoglycemia: 80 mg/dL
Raskin, 2003[57]	MDI	MDI 4+ times/day Short acting: aspart Long acting: NPH	NA	NA	24 wks	Titration guidelines: Yes Between visit guidelines: No FG: 80-120 mg, 4.4-6.7 mmol	NA
Raskin, 2003[57]	CSII	MM 507c Short acting: aspart	NA	Yes	24 wks	Titration guidelines: Yes Between visit guidelines: No FG: 80-120 mg, 4.4-6.7 mmol	NA
Rigla, 2008[91]	MDI	NA	SMBG Monitor use: NA Fingerstick: Other	NA	4 wks	Titration guidelines: No Between visit guidelines NR Targets NR	NA
Rigla, 2008[91]	CSII	NA	MM guardian rtCGM Monitor use: 3 days/wk Fingerstick: Other	NA	4 wks	Titration guidelines NR Between visit guidelines NR Targets NR	NR
Schiaffini, 2005[39]	MDI	MDI 4+ times/day Short acting: NR Long acting: glargine	NA	NA	12 mo	Titration guidelines: Yes Between visit guidelines NR Targets NR	NA
Schiaffini, 2005[39]	CSII	MM 508, DR DTRON, DR HTron v100 Short acting: lispro	NA	Yes	12 mo	Titration guidelines: Yes Between visit guidelines NR Targets NR	NA

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Schiaffini, 2007[34]	MDI	MDI 4+ times/day Short acting: Reg insulin Long acting: glargine	NA	NA	24 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Schiaffini, 2007[34]	CSII	pump unspec., Short acting: lispro	NA	NR	24 mo	Titration guidelines: Yes Between visit guidelines: Yes Targets NR	NA
Skogsberg, 2008[31]	MDI	MDI 4+ times/day Short acting: aspart Long acting: NPH	NA	NA	24 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Skogsberg, 2008[31]	CSII	DR HTron v100 Short acting: aspart	NA	Yes	24 mo	Titration guidelines NR Between visit guidelines NR Targets NR	NA
Tamborlane, 2008[68]	NA	NA	SMBG Monitor use: NA Fingerstick: 4+ times/day	NA	26 wks	Titration guidelines NR Between visit guidelines: Yes Preprandial: 70-130 mg, other target: 100-150 mg	NA
Tamborlane, 2008[68]	NA	NA	Dexcom sts, MM paradigm, Abbott freestyle navigator Monitor use: daily Fingerstick: NR	NA	26 wks	Titration guidelines NR Between visit guidelines: Yes Preprandial: 70-130 mg, other target: 100-150 mg	NR

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Thomas, 2007[47]	MDI	MDI 4+ times/day Short acting: lispro Long acting: glargine	NA	NA	24 wks	Titration guidelines: Yes Between visit guidelines: Yes Other target: avoid glucose < 4 mmol/L	NA
Thomas, 2007[47]	CSII	MM 508, Short acting: lispro	NA	Yes	24 wks	Titration guidelines: Yes Between visit guidelines: Yes Other target: avoidance of glucose < 4 mmol/l	NA
Tsui, 2001[52]	MDI	MDI 4+ times/day Short acting: lispro Long acting: NPH	NA	NA	9 mo	Titration guidelines NR Between visit guidelines: Yes Preprandial: 4.0-6.0 mmol, 2 hr postprandial: <9 mmol	NA
Tsui, 2001[52]	CSII	Minmed 507 Short acting: lispro	 NA	Yes	9 mo	Titration guidelines NR Between visit guidelines: Yes Preprandial: 4.0-6.0 mmol, 2 hr postprandial: <9 mmol	NA
Volpe, 2010[59]	MDI	MDI 4+ times/day Short acting: short insulin analogue Long acting: NPH	NA	NA	36.4 wks	Titration guidelines NR Between visit guidelines: No Preprandial: 90 mg, other target: 1-hr PPG < 130 mg	NA
Volpe, 2010[59]	CSII	pump unspec.,	SMBG Monitor use: NA Fingerstick: 4+ times/day	Yes	36.4 wks	Titration guidelines NR Between visit guidelines: No Preprandial: 90 mg, other target: 1-hr PPG < 130 mg	NR

Table 3. Interventions evaluated in studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	CSII or MDI	Pump type Number of injections Insulin used	BGM type Monitor use Fingerstick frequency	Training?	Duration of therapy	Provider titration guidelines? Glycemic targets?	Alarms
Wainstein, 2005[58]	MDI	MDI 4+ times/day Short acting: Reg insulin Long acting: NPH	Monitor use: NA	NR	18 wks	Titration guidelines: Yes Between visit guidelines NR Target HbA1c: 7	NA
Wainstein, 2005[58]	CSII	pump unspec. Short acting: lispro	NA	NR	48 wks	Titration guidelines: Yes Between visit guidelines: Yes Target HbA1c: 7	NA
Weintrob, 2003[42]	MDI	MDI 4+ times/day Short acting: Reg insulin Long acting: NPH	NA	NA	3.5 mo	Titration guidelines: Yes Between visit guidelines: Yes Preprandial: 4.4-8.3 mmol, 2 hr postprandial: 6.6-10 mmol, other target: 4.4-8.3 mmol/L	NA
Weintrob, 2003[42]	CSII	MM 508 Short acting: lispro	NA	Yes	3.5 mo	Titration guidelines: Yes Between visit guidelines: Yes Preprandial: 4.4-8.3 mmol, 2 hr postprandial: 6.6-10 mmol, other target: 4.4-8.3 mmol/L	NA
Yoo, 2008[92]	MDI	NA	SMBG Monitor use: NA Fingerstick: Other	NA	3 mo	Titration guidelines: No Between visit guidelines: No Targets NR	NA
Yoo, 2008[92]	CSII	NA	MM guardian rtCGM Monitor use: Once/month for 3 days Fingerstick: 3+ times/day	NA	3 mo	Titration guidelines: No Between visit guidelines: No Targets NR	Hyperglycemia: 300 mg/dL Hypoglycemia: 60 mg/dL

Abbreviations: CSII = continuous subcutaneous insulin infusion; dL = deciliter; FG = fasting glucose; hr = hour; MDI = multiple daily injections; mg = milligram; MM = Medtronic Minimed; mmol = micromoles; mo = month; NA = not applicable; NR = not reported; PPG = post prandial glucose; reg.= regular; rtCGM = real time continuous glucose monitor; SMBG = self monitoring of blood glucose; unspec. = unspecified; wk = week; yr = year

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Bergenstal, 2010[72]	MDI + SMBG, 241	CSII + rtCGM, 244	HbA1c (%)	1 years		G2-G1: Mean, -0.6 (95% CI, -0.7--0.4); P: <0.001
Bergenstal, 2010[72]	MDI + SMBG, 248	CSII + rtCGM, 247	Severe hypoglycemia (require assistance + (BG<50 mg/dl or recovery with glucose treatment))	1 years	Incidence 17 (7) Events 27 events 13.48 events / 100 person-years; P: 0.84	Incidence 21 (9) Events 32 events 13.31 events / 100 person-years
Bergenstal, 2010[72] ≥19 years (adults)	MDI + SMBG, 163	CSII + rtCGM, 166	Weight gain (kg)	1 years	F-B: Mean, 1.8	F-B: Mean, 2.4 G2-G1: 0.6; P: 0.19
Bin-Abbas, 2006[36]	MDI, 8	CSII, 14	HbA1c (%)	6 months	B: Mean, 10.1 F: Mean, 8.5; P: 0.016 F-B: Mean, 8.5; P: 0.0005 vs. baseline	B: Mean, 10.2 F: Mean, 7.5 F-B: Mean, 7.5; P: 0.0001 vs. baseline G2-G1: -1
Bin-Abbas, 2006[36]	MDI, 8	CSII, 14	HbA1c (%)	6 months	B: Mean, 10.1 F: Mean, 8.5; P: 0.016 F-B: Mean, 8.5; P: 0.0005 vs. baseline	B: Mean, 10.2 F: Mean, 7.5 F-B: Mean, 7.5; P: 0.0001 vs. baseline G2-G1: -1
Bolli, 2009[45]	MDI, 26	CSII, 24	HbA1c (%)	24 weeks	F-B: Mean, -0.6 (SD, 0.8)	F-B: Mean, -0.7 (SD, 0.7) G2-G1: Mean, -0.1 (-0.5-0.3); P: NR
Bolli, 2009[45]	MDI, 26	CSII, 24	Hyperglycemia (Fasting glucose: before breakfast)	24 weeks		G2-G1: -0.7 (95% CI, -1.8-0.5)
Bolli, 2009[45]	MDI, 26	CSII, 24	Hyperglycemia (Fasting glucose: preprandial' - before other meal (besides breakfast))	24 weeks		G2-G1: Mean, -0.9 (95% CI, -2.3-0.4)
Bolli, 2009[45]	MDI, 26	CSII, 24	Hyperglycemia (Postprandial glucose: 2 hour after meal)	24 weeks		G2-G1: Mean, 0.3 (95% CI, -1.1-1.7); P: NR
Bolli, 2009[45]	MDI, 26	CSII, 24	Hyperglycemia (Postprandial glucose: glucose at 3 am)	24 weeks		G2-G1: Mean, 3 (95% CI, -0.4-6.5); P: NR

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Bolli, 2009[45]	MDI	CSII	Hypoglycemia (Mild hypoglycemia: symptomatic + no assistance needed + PG<4 mmol/l)	24 weeks	Events 31 events / person; P: 0.97	Events 35 events / person
Bolli, 2009[45]	MDI	CSII	Hypoglycemia frequency (Mild hypoglycemia: ANY hypoglycemia)	24 weeks	Events 35 events / patient; P: 0.93	Events 41 events / patient
Bolli, 2009[45]	MDI	CSII	Hypoglycemia frequency (Mild hypoglycemia: asymptomatic' not mild)	24 weeks	Events 1.4 events / patient; P: 0.95	Events 1.2 events / patient
Bolli, 2009[45]	MDI	CSII	Hypoglycemia frequency (Mild hypoglycemia: symptomatic, not necessary mild)	24 weeks	Events 13 events / patient; P: 0.84	Events 14 events / patient
Bolli, 2009[45]	MDI	CSII	Hypoglycemia frequency (Nocturnal hypoglycemia: between bedtime and rising)	24 weeks	Events 5 events / patient; P: 0.34	Events 3 events / patient
Bolli, 2009[45]	MDI, 26	CSII, 24	Severe hypoglycemia (symptoms+ assistance needed+(PG<2 mmol/l OR prompt recovery with glucose/glucagon))	24 weeks	Incidence 2 (8) Events 2	Incidence 2 (8) Events 2
Bruttomesso, 2008[46]	MDI, 39	CSII, 39	Hyperglycemia (severe: >20 mmol/l at any time)	4 months	Events 1.3 events / patient; P: 0.327	Events 1.1 events / patient
Bruttomesso, 2008[46]	MDI, 39	CSII, 39	Hypoglycemia frequency (Mild hypoglycemia: 2.0-3.5 mmol/l)	4 months	Events 7.8 events / patient; P: 0.775	Events 8 events / patient

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Bruttomesso, 2008[46]	MDI, 39	CSII, 39	Hypoglycemia frequency (Moderate hypoglycemia: not defined)	4 months	Events 12.3 events / patient; P: 0.011	Events 9.5 events / patient
Bruttomesso, 2008[46]	MDI, 39	CSII, 39	Severe hypoglycemia (< 2mmol/l)	4 months	Events 0.1; P: 0.71	Events 0.1
Bruttomesso, 2008[46]	MDI	CSII	Weight gain	4 months	"Remained unchanged"	
Cohen, 2003[41]	MDI, 13	CSII, 15	HbA1c (%)	12 months	B: Mean, 8.48 (SD, 1.4) F: Mean, 8.57 (SD, 0.44); P: ns ns F-B: 0.09	B: Mean, 8.58 (SD, 0.82) F: Mean, 8.15 (SD, 1.3) F-B: -0.43 G2-G1: -0.52
Cohen, 2003[41]	MDI, 13	CSII, 15	Hypoglycemia frequency (Daytime hypoglycemia: Mean/patient/study period)	12 months	F: Mean, 15.1 (SD, 16.1)	F: Mean, 11.4 (SD, 7.1)
Cohen, 2003[41]	MDI, 13	CSII, 15	Hypoglycemia frequency (Nocturnal hypoglycemia: Mean/patient/study period)	12 months	F: Mean, 4 (SD, 6.5)	F: Mean, 3 (SD, 3.5)
Cohen, 2003[41]	MDI, 13	CSII, 15	Severe hypoglycemia (Events)	12 months	Events 4; P: NS	Events 1
Cohen, 2003[41]	MDI	CSII	Weight gain (BMI-SDS)	12 months	F: 0.25 (SD, 0.44)	F: 0.23 (SD, 0.45)
Cypryk, 2008[60]	MDI, 78	CSII, 25	Birth weight (kg)	36 weeks (3rd trimester)	F: Mean, 3270 (SD, 894)	F: Mean, 3191 (SD, 903)
Cypryk, 2008[60]	MDI, 78	CSII, 25	Birth weight (LGA)	36 weeks (3rd trimester)	Incidence 22 (28.6); P: 0.1159	Incidence 3 (12)
Cypryk, 2008[60]	MDI, 78	CSII, 25	Birth weight (SGA)	36 weeks (3rd trimester)	Incidence 7 (9.1); P: 0.7818	Incidence 3 (12)

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Cypryk, 2008[60]	MDI, 78	CSII, 25	Cesarean delivery (Not further specified)	36 weeks (3rd trimester)	Incidence 54 (69.2); P: 0.2354	Incidence 14 (46)
Cypryk, 2008[60]	MDI, 78	CSII, 25	Frequency of neonatal hypoglycemia (<40 mg/dL)	36 weeks (3rd trimester)	Incidence 11 (14.1); P: 0.8902	Incidence 4 (16)
Cypryk, 2008[60]	MDI, 78	CSII, 25	Gestational age (weeks)	(3rd trimester)	F: Mean, 36.3 (SD, 3.2); P: 0.5805	F: Mean, 36.6 (SD, 2.4)
Cypryk, 2008[60]	MDI, 86	CSII, 30	HbA1c (%)	(3rd trimester)	F: Mean, 6.8 (SD, 1.2)	F: Mean, 6.4 (SD, 1)
Cypryk, 2008[60]	MDI, 86	CSII, 30	HbA1c (%)	(1st trimester)	F: Mean, 7.7 (SD, 2.4)	F: Mean, 7.4 (SD, 1.7)
Cypryk, 2008[60]	MDI, 86	CSII, 30	HbA1c (%)	(2nd trimester)	F: Mean, 6.6 (SD, 0.9)	F: Mean, 6.5 (SD, 1.1)
Cypryk, 2008[60]	MDI, 86	CSII, 30	Minor anomalies (congenital abnormalities, unspecified)	36 weeks (3rd trimester)	Incidence 2 (2); P: 0.05	Incidence 4 (13)
Cypryk, 2008[60]	MDI, 86	CSII, 30	Severe hypoglycemia (required treatment with parenteral glucagon administered by a third party)	36 weeks (3rd trimester)	Incidence 0 (0)	Incidence 0 (0)
Deiss, 2006[70]	SMBG	rtCGM	HbA1c (%)	3 months	B: Mean, 9.7 (SD, 1.3) F-B: Mean, 0.4 (SD, 1)	B: Mean, 9.6 (SD, 1.2) F-B: Mean, 0.7 (SD, 1.3) G2-G1: 0.3
Deiss, 2006[70]	SMBG	rtCGM	HbA1c (%)	3 months	B: Mean, 9.7 (SD, 1.3) F-B: Mean, 0.4 (SD, 1)	B: Mean, 9.5 (SD, 1.1) F-B: Mean, 1 (SD, 1.1) G2-G1: 0.6
Deiss, 2006[70]	SMBG	rtCGM	Hypoglycemia frequencySevere hypoglycemia (not further spec)	3 months		Events 1
Deiss, 2006[70]	SMBG	rtCGM	Hypoglycemia frequencySevere hypoglycemia (not further spec)	3 months		Events 1

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Derosa, 2009[56]	MDI, 32	CSII, 32	HbA1c (%)	12 months	B: Mean, 9.3 (SD, 2.1) F: Mean, 8.2 (SD, 1); P: <0.05 F-B: -1.1	B: Mean, 9.2 (SD, 2) F: Mean, 7.6 (SD, 0.8) F-B: -1.6 G2-G1: -0.5
DeVries, 2002[51]	MDI, 40	CSII, 39	HbA1c (%)	16 weeks	B: Mean, 9.25 (SD, 1.4) F-B: Mean, -0.07 (SD, 0.7) G2-G1: Mean, 0.84 (95% CI, 0.36-1.31)	B: Mean, 9.27 (SD, 1.4) F-B: Mean, -0.91 (SD, 1.28) G2-G1: P: 0.002
DeVries, 2002[51]	MDI, 40	CSII, 39	Hyperglycemia (Fasting glucose: 5-hr after bedtime)	16 weeks	F: Mean, 9.8; P: NS	F: Mean, 9.8
DeVries, 2002[51]	MDI, 40	CSII, 39	Hyperglycemia (Fasting glucose: before bedtime glucose)	16 weeks	F: Mean, 11.8; P: NS	F: Mean, 10.8
DeVries, 2002[51]	MDI, 40	CSII, 39	Hyperglycemia (Fasting glucose: before breakfast glucose)	16 weeks	F: Mean, 10; P: NS	F: Mean, 8.5
DeVries, 2002[51]	MDI, 40	CSII, 39	Hyperglycemia (Fasting glucose: before dinner glucose)	16 weeks	F: Mean, 10.2; P: NS	F: Mean, 8.3
DeVries, 2002[51]	MDI, 40	CSII, 39	Hyperglycemia (Fasting glucose: before lunch glucose)	16 weeks	F: Mean, 9	F: Mean, 7.8
DeVries, 2002[51]	MDI, 40	CSII, 39	Hyperglycemia (Postprandial glucose: 90-min after breakfast)	16 weeks	F: Mean, 10.5; P: NS	F: Mean, 8.3
DeVries, 2002[51]	MDI, 40	CSII, 39	Hyperglycemia (Postprandial glucose: 90-min after dinner)	16 weeks	F: Mean, 8.7; P: NS	F: Mean, 9
DeVries, 2002[51]	MDI, 40	CSII, 39	Hyperglycemia (Postprandial glucose: 90-min after lunch)	16 weeks	F: Mean, 9.7; P: NS	F: Mean, 8.2

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
DeVries, 2002[51]	MDI, 40	CSII, 39	Hypoglycemia frequency (Mild hypoglycemia: (SMBG < 3.9 mmol/L))	16 weeks	Episodes per patient-week B: Mean, 1.97 (SD, 1.53) F-B: Mean, -0.02 (SD, 1.18) G2-G1: Mean, -0.99 (-1.87--0.11)	Episodes per patient-week B: Mean, 2.13 (SD, 2.05) F-B: Mean, 0.98 (SD, 2.02)
DeVries, 2002[51]	MDI, 40	CSII, 39	Severe hypoglycemia (requires 3rd party assistance)	16 weeks	Incidence 6 (15); P: 0.48	Incidence 3 (8)
DeVries, 2002[51]	MDI, 40	CSII, 39	Weight gain (kg)	16 weeks	B: Mean, 79.8 (SD, 13.5) F-B: Mean, 0.88 (SD, 2.74) G2-G1: Mean, 0.28 (95% CI, -1.07-1.63)	B: Mean, 77.3 (SD, 13.6) F-B: Mean, 0.6 (SD, 2.94)
Doyle, 2004[40]	MDI, 16	CSII, 16	HbA1c (%)	16 weeks	B: Mean, 8.2 (SD, 1.1) F: 8.1 (1.2) F-B: -0.1	B: Mean, 8.1 (SD, 1.2) F: 7.2 (1) F-B: -0.9 G2-G1: -0.8
Doyle, 2004[40]	MDI	CSII, 16	Hypoglycemia frequency (Nocturnal hypoglycemia: not specified)	16 weeks		Incidence 2 (12) Events 2
Doyle, 2004[40]	MDI, 16	CSII	Severe hypoglycemia (not further spec)	16 weeks	Incidence 4 (25) Events 5	
Doyle, 2004[40]	MDI, 16	CSII, 16	Weight gain		F-B: Mean, <1 kg/m2; P: NS vs. baseline	
Garcia-Garcia, 2007[35]	MDI, 24	CSII, 8	HbA1c (%)	24 months	B: Mean, 7.82 (SD, 0.7) F: Mean, 7.54 (SD, 0.74); P: 0.8 0.8 F-B: -0.28	B: Mean, 7.62 (SD, 0.62) F: Mean, 7.7 (SD, 0.64) F-B: 0.08 G2-G1: 0.36
Garcia-Garcia, 2007[35]	MDI, 24	CSII, 8	Ratio of basal to bolus insulin (Proportion of basal insulin)	24 months	F: Mean, 45.6 (SD, 5.2); P: 0.5	F: Mean, 47.3 (SD, 5.3)

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Garcia-Garcia, 2007[35]	MDI, 24	CSII, 8	Severe hypoglycemia (Severe hypoglycemia/patient/year)	24 months	F: Mean, 0.04 (SD, 0.14); P: 0.8	F: Mean, 0 (SD, 0)
Hanaire-Broutin, 2000[53]	MDI + rtCGM, 41	CSII + SMBG, 41	Hyperglycemia (Postprandial glucose: mean daily blood glucose (pre- and postprandial) recorded during last 14 days of each period)	4 months	F: Mean, 175 (SD, 33); P: <0.05	F: Mean, 165 (SD, 27)
Hanaire-Broutin, 2000[53]	MDI + rtCGM, 41	CSII + SMBG, 41	Hypoglycemia frequency (Mild hypoglycemia: defind as BG levels <60 mg/dl)	4 months	Events 4.3 events / 14 day; P: NS	Events 3.9 events / 14 day
Hanaire-Broutin, 2000[53]	MDI + rtCGM, 41	CSII + SMBG, 41	Severe hypoglycemia (as defined by DCCT)	4 months	Incidence 1 (2) Events 1 events / 4 months	Incidence 2 (5) Events 3 events / 4 months
Herman, 2005[55]	MDI, 54	CSII, 53	HbA1c (%)	12 months	B: Mean, 8.1 (SD, 1.2) F: Mean, 6.4 (SD, 0.8); P: 0.19 F-B: Mean, -1.6 (SD, 1.2); P: <0.0001 vs. baseline	B: Mean, 8.4 (SD, 1.1) F: Mean, 6.6 (SD, 0.8) F-B: Mean, -1.7 (SD, 1); P: <0.0001 vs. baseline G2-G1: -0.1; P: 0.19
Herman, 2005[55]	MDI, 54	CSII, 53	Hypoglycemia frequency (Mild hypoglycemia: Capillary BG < 65 mg/dl treated by patient or symptoms that resolved with oral glucose)	12 months	Incidence 49 (90); P: 0.17	Incidence 43 (81)

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Herman, 2005[55]	MDI, 54	CSII, 53	Severe hypoglycemia (confusion, LOC, seizures + (BG<50 OR resolution of symptoms with glucose/glucagon from another person))	12 months	Incidence 6 (11); P: 0.49 Events 12 events / 51.43 person-years; P: 0.61	Incidence 3 (6) Events 4 events / 49.87 person-years
Herman, 2005[55]	MDI, 54	CSII	Severe hypoglycemia (resulting in life-threatening injury to patient/ other person, hospitalization, or death)	12 months	Incidence 1 (2) Events 1	
Herman, 2005[55]	MDI, 54	CSII, 53	Weight gain (kg)	12 months	F-B: Mean, 2.6; P: <0.001 vs. baseline	F-B: Mean, 2.1; P: <0.001 vs. baseline G2-G1: -0.5; P: 0.7
Hieronimus, 2005[62]	MDI, 23	CSII, 33	Birth weight (kg)	(3rd trimester)	F: Mean, 3.384 (SD, 0.693); P: 0.036	F: Mean, 3.767 (SD, 0.751)
Hieronimus, 2005[62]	MDI, 23	CSII, 33	Cesarean delivery (Not further specified)	(3rd trimester)	Incidence 8 (34.6); P: 0.016	Incidence 23 (70)
Hieronimus, 2005[62]	MDI, 23	CSII, 33	Gestational age (weeks)		F: Mean, 37.2 (SD, 1.2); P: >0.05	F: Mean, 37 (SD, 1.6)
Hieronimus, 2005[62]	MDI, 23	CSII, 33	Major anomalies (Number of infants)	(3rd trimester)	Incidence 3 (13); P: >0.05	Incidence 4 (12)
Hieronimus, 2005[62]	MDI, 23	CSII, 33	NICU admission (Number of infants)	(3rd trimester)	Incidence 8 (35); P: >0.05	Incidence 11 (33)
Hieronimus, 2005[62]	MDI, 23	CSII, 33	Severe hypoglycemia (not further spec)	(3rd trimester)	Incidence 2 (9); P: >0.05	Incidence 3 (9)
Hieronimus, 2005[62]	MDI, 23	CSII, 33	Weight gain (kg)	(3rd trimester)	F: Mean, 14.4 (SD, 5.2); P: >0.05	F: Mean, 14.5 (SD, 3.9)
Hirsch, 2005[49]	MDI, 50	CSII, 50	Hyperglycemia (Postprandial glucose: SMBG 2h after breakfast)	5 weeks	F: Mean, 182 (SD, 82); P: NS	F: Mean, 158 (SD, 63)

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Hirsch, 2005[49]	MDI, 50	CSII, 50	Hyperglycemia (Postprandial glucose: SMBG after dinner)	5 weeks	F: Mean, 159 (SD, 77); P: NS	F: Mean, 144 (SD, 64)
Hirsch, 2005[49]	MDI, 50	CSII, 50	Hyperglycemia (Preprandial glucose: SMBG before dinner)	5 weeks	F: Mean, 148 (SD, 71); P: NS	F: Mean, 128 (SD, 58)
Hirsch, 2005[49]	MDI, 100	CSII, 100	Hypoglycemia frequency (Daytime hypoglycemia: minor (asymptomatic and <50 or managed by patient and <50), 0800 - 0000)	5 weeks	Incidence 59 (60) Events 232; P: <0.001	Incidence 59 (60) Events 333
Hirsch, 2005[49]	MDI, 100	CSII, 100	Hypoglycemia frequency (Daytime hypoglycemia: symptomatic, not confirmed by measurement, 0800 - 0000)	5 weeks	Incidence 64 (65) Events 305; P: 0.0124	Incidence 70 (71) Events 403
Hirsch, 2005[49]	MDI, 100	CSII, 100	Hypoglycemia frequency (Mild hypoglycemia: Daily hypoglycemia which was either asymptomatic but glucose <50 or symptomatic, glucose<50, and patient managed)	5 weeks	Incidence 68 (69) Events 387; P: 0.2099	Incidence 72 (74) Events 387
Hirsch, 2005[49]	MDI, 100	CSII, 100	Hypoglycemia frequency (Moderate hypoglycemia: daily' and symptomatic but not confirmed with measurement)	5 weeks	Incidence 71 (72) Events 434 events; P: 0.0506	Incidence 73 (75) Events 507 events

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Hirsch, 2005[49]	MDI, 100	CSII, 100	Hypoglycemia frequency (Nocturnal hypoglycemia: minor (asymptomatic and glucose <50 OR symptomatic, glucose <50, and patient managed), 0000 - 0800)	5 weeks	Incidence 49 (50) Events 155; P: 0.002	Incidence 51 (52) Events 110
Hirsch, 2005[49]	MDI, 100	CSII, 100	Hypoglycemia frequency (Nocturnal hypoglycemia: symptomatic, not confirmed by measurement, between 0000 and 0800)	5 weeks	Incidence 47 (48) Events 125; P: 0.7211	Incidence 41 (42) Events 104
Hirsch, 2005[49]	MDI, 100	CSII, 100	Severe hypoglycemia (severe CNS symptoms and pt unable to manage with either glucose <50 or improvement with food/ glucagon/ IV glucose)	5 weeks	Incidence 3 (3) Events 5	Incidence 2 (2) Events 2
Hirsch, 2008[69]	SMBG, 72	rtCGM, 66	HbA1c (%)	6 months	Incidence 12 (17); P: 0.0031 Least square mean change from baseline, 0.5879; SE, 0.0891; B: Mean, 8.39 (SD, 0.64) F: Mean, 7.84 (SD, 0.81) F-B: Mean, -0.56 (SD, 0.72)	Incidence 16 (24) Least square mean change from baseline, -0.7002; SE, 0.0887 B: Mean, 8.49 (SD, 0.76) F: Mean, 7.77 (SD, 0.92) F-B: Mean, -0.71 (SD, 0.71) G2-G1: -0.15

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Hirsch, 2008[69]	SMBG, 72	rtCGM, 66	Hyperglycemia	6 months	B: Mean, 2.667 (SD, 0.649) F-B: Mean, 2.657 (SD, 0.805); P: 0.7671 vs. baseline	B: Mean, 2.635 (SD, 0.635) F-B: Mean, 2.869 (SD, 0.913); P: 0.0301 vs. baseline G2-G1: 0.21
Hirsch, 2008[69]	SMBG, 72	rtCGM, 66	Hypoglycemia frequency (Moderate hypoglycemia: <70 mg/dL)	6 months	B: Mean, 0.8348 (SD, 0.728) F: Mean, 1.1663 (SD, 0.744); 0.6154 F-B: 0.33	B: Mean, 0.8378 (SD, 0.725) F: Mean, 0.8828 (SD, 0.756) F-B: 0.05 G2-G1: -0.29
Hirsch, 2008[69]	SMBG, 72	rtCGM, 66	Severe hypoglycemia (clinical episode of hypoglycemia resulting in seizure or coma, requiring hospitalization or intravenous glucose or glucagon, or any hypoglycemia requiring assistance)	6 months	Events 3; P: 0.04	Events 11
Hoogma, 2006[48]	MDI, 256	CSII, 256	Hypoglycemia frequency (Mild hypoglycemia: self treated)	8 months	Events 55.4 events / 1 person-years; P: 0.001 RR, 1.12; CI, 1.08 - 11.17	Events 49.3 events / 1 person-years
Hoogma, 2006[48]	MDI, 256	CSII, 256	Severe hypoglycemia (requiring outside assistance)	8 months	Events 0.5 events / 1 person-years; P: <0.001 RR, 2.6; CI, 2.08 - 3.25	Events 0.2 events / 1 person-years
JDRF CGM Study Group, 2009[66]	SMBG, 62	rtCGM, 67	(Moderate hypoglycemia: minutes per day spent at glucose level </=60 mg/dl)	26 weeks	B: Median, 40 F: Median, 35; P: 0.05 F-B: -5	B: Median, 40 F: Median, 18 F-B: -22 G2-G1: -17
JDRF CGM Study Group, 2009[66]	SMBG, 62	rtCGM, 67	(Moderate hypoglycemia: minutes per day spent with glucose level ≤ 50 mg/dl)	26 weeks	B: Median, 9 F: Median, 8; P: 0.12 F-B: -1	B: Median, 7 F: Median, 4 F-B: -3 G2-G1: -2

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
JDRF CGM Study Group, 2009[66]	SMBG, 62	rtCGM, 67	HbA1c (%)	26 weeks	Incidence 38 (61); P: <0.001 B: Mean, 6.5 (SD, 0.3) F: Mean, 6.8 (SD, 0.5) F-B: Mean, 0.33 (SD, 0.43) G2-G1: Mean, -0.34 (95% CI, -0.2--0.49)	Incidence 59 (88) B: Mean, 6.4 (SD, 0.5) F: Mean, 6.4 (SD, 0.5) F-B: Mean, 0.02 (SD, 0.45) G2-G1: P: <0.001
JDRF CGM Study Group, 2009[66]	SMBG, 62	rtCGM, 67	Hyperglycemia	26 weeks	B: Median, 972 F: 949; P: 0.003 F-B: -23	B: Median, 1063 F: 1063 F-B: 0 G2-G1: 23
JDRF CGM Study Group, 2009[66]	SMBG, 62	rtCGM, 67	Hyperglycemia	26 weeks	B: Median, 63 F: 82; P: 0.09 F-B: 19	B: Median, 40 F: 48 F-B: 8 G2-G1: -11
JDRF CGM Study Group, 2009[66]	SMBG, 62	rtCGM, 67	Hyperglycemia	26 weeks	B: Median, 331 F: Median, 341; P: 0.1 F-B: 10	B: Median, 255 F: Median, 283 F-B: 28 G2-G1: 18
JDRF CGM Study Group, 2009[66]	SMBG, 62	rtCGM, 67	Hypoglycemia frequency (Mild hypoglycemia: median minutes per day spent at a glucose level </= 70 mg/dl)	26 weeks	B: 96 F: Median, 91; P: 0.43 vs. baseline0.002 vs. baseline F-B: -5	B: 91 F: Median, 54 F-B: -37 G2-G1: -32
JDRF CGM Study Group, 2009[66]	SMBG	rtCGM	Hypoglycemia frequency (Moderate hypoglycemia: >20 min with glucose level <54 mg/dl)	26 weeks	Events 0.47 events / 24 hours; P: 0.07	Events 0.25 events / 24 hours

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
JDRF CGM Study Group, 2009[66]	SMBG, 62	rtCGM, 67	Severe hypoglycemia (event that required assistance to administer carbohydrate, glucagon, or other resuscitative actions)	26 weeks	Incidence 7 (11)	Incidence 7 (10)
Kernaghan, 2008[61]	MDI, 18	CSII, 24	Birth weight (Z score)	37 weeks (3rd trimester)	F: Mean, 2; P: 0.86	F: Mean, 2.09
Kernaghan, 2008[61]	MDI, 18	CSII, 24	Gestational age (weeks)	37 weeks (3rd trimester)	F: Median, 37.5; P: 0.28	F: Median, 36.5
Kernaghan, 2008[61]	MDI, 18	CSII, 24	HbA1c (%)	(2nd trimester)	B: Mean, 8.01 F: Mean, 6.6; P: 0.27 F-B: -1.41	B: Mean, 7.62 F: Mean, 6.3 F-B: -1.32 G2-G1: 0.09
Kernaghan, 2008[61]	MDI, 18	CSII, 24	HbA1c (%)	(1st trimester)	B: Mean, 8.01 F: Mean, 7.3; P: 0.41 F-B: -0.71	B: Mean, 7.62 F: Mean, 6.95 F-B: -0.67 G2-G1: 0.04
Kernaghan, 2008[61]	MDI, 18	CSII, 24	HbA1c (%)	37 weeks (3rd trimester)	B: Mean, 8.01 F: Mean, 6.44; P: 0.51 F-B: -1.57	B: Mean, 7.62 F: Mean, 6.63 F-B: -0.99 G2-G1: 0.58
Kernaghan, 2008[61]	MDI, 18	CSII, 24	Minor anomalies (congenital abnormalities, unspecified)	37 weeks (3rd trimester)	Incidence 0 (0)	Incidence 0 (0)
Kordonouri, 2006[37] <12 years	MDI, 23	CSII, 23	HbA1c (%)	1 years	B: Mean, 7.98 (SD, 0.9) F: Mean, 8.31 (SD, 0.85); P: 0.033 F-B: 0.33	B: Mean, 7.97 (SD, 0.93) F: Mean, 7.97 (SD, 0.82) F-B: 0 G2-G1: -0.33
Kordonouri, 2006[37] ≥12 years	MDI, 29	CSII, 29	HbA1c (%)	1 years	B: Mean, 8.32 (SD, 1.1) F: Mean, 8.67 (SD, 1.4); P: 0.572 F-B: 0.35	B: Mean, 8.32 (SD, 1.09) F: Mean, 8.51 (SD, 1.1) F-B: 0.19 G2-G1: -0.16

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Kordonouri, 2006[37]	MDI, 52	CSII, 52	Severe hypoglycemia (Incidence per 100 patient-years)	1 years	B: Mean, 28.8 (SD, 8.8) F: Mean, 23.1 (SD, 10.5); P: 0.107 F-B: -5.7	B: Mean, 19.2 (SD, 7.3) F: Mean, 5.8 (SD, 3.3) F-B: -13.4 G2-G1: -7.7
Kordonouri, 2010[64]	CSII + SMBG, 77	CSII + rtCGM, 76	HbA1c (%)	52 weeks	Incidence 26 (34); P: 0.464 B: Mean, 11.5 (SD, 2.2) F: Mean, 7.6 (SD, 1.4); P: 0.451 F-B: -3.9	Incidence 30 (39) B: Mean, 11.2 (SD, 2.1) F: Mean, 7.4 (SD, 1.2) F-B: -3.8 G2-G1: 0.1
Kordonouri, 2010[64]	CSII + SMBG, 78	CSII + rtCGM, 76	Ratio of basal to bolus insulin (Number of daily boluses)	52 weeks	F: Mean, 7 (SD, 2.7); P: 0.097	F: Mean, 7.9 (SD, 3.6)
Kordonouri, 2010[64]	CSII + SMBG, 78	CSII + rtCGM, 76	Ratio of basal to bolus insulin (Proportion of basal insulin)	52 weeks	F: Mean, 29.7 (SD, 10.4)	F: Mean, 34 (SD, 11.8)
Kordonouri, 2010[64]	CSII + SMBG, 78	CSII + rtCGM, 76	Severe hypoglycemia (not further spec)	52 weeks	Incidence 4 (5); P: 0.046	Incidence 0 (0)
Lee, 2007[74]	SMBG, 8	rtCGM, 9	HbA1c (%)	15 weeks	B: Mean, 8.58 (SD, 1.3) F: Mean, 7.5 (SD, 1.01) F-B: Mean, -1.08; P: 0.04 vs. baseline	B: Mean, 9.45 (SD, 0.55) F: Mean, 7.4 (SD, 0.66) F-B: Mean, -2.05; P: 0.0004 vs. baseline G2-G1: -0.97; P: 0.02
Lee, 2007[74]	SMBG, 8	rtCGM, 8	Severe hypoglycemia (not further spec)	15 weeks	Incidence 0 (0)	Incidence 0 (0)
Lepore, 2003[50]	MDI, 16	CSII, 16	HbA1c (%)	1 years	F-B: NR	F-B: NR
Lepore, 2003[50]	MDI, 16	CSII, 16	Hyperglycemia (Fasting glucose (mg/dL))	1 years	F-B: NR; P: NS vs. baseline	F-B: NR
Lepore, 2003[50]	MDI, 16	CSII, 16	Severe hypoglycemia	1 years	“number of severe hypoglycemic episodes decreased”	“number of severe hypoglycemic episodes decreased”
Lepore, 2003[50]	MDI	CSII	Weight gain	1 years	NR	“not associated with weight gain”
Minkina-Pedras, 2005[38]	MDI, 25	CSII, 35	Daily insulin requirement	18 months	B: Mean, 0.68 (SD, 0.2) F: Mean, 0.84 (SD, 0.19) F-B: 0.16	B: Mean, 0.84 (SD, 0.27) F: Mean, 0.85 (SD, 0.18) F-B: 0.01 G2-G1: -0.15

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Minkina-Pedras, 2005[38]	MDI, 25	CSII, 30	Daily insulin requirement	18 months	B: Mean, 0.68 (SD, 0.2) F: Mean, 0.84 (SD, 0.19) F-B: 0.16	B: Mean, 0.86 (SD, 0.28) F: Mean, 0.77 (SD, 0.13) F-B: -0.09 G2-G1: -0.25
Minkina-Pedras, 2005[38]	MDI, 25	CSII, 30	HbA1c (%)	18 months	F: Mean, 7.3 (SD, 1)	F: Mean, 6.9 (SD, 0.53)
Minkina-Pedras, 2005[38]	MDI, 25	CSII, 35	HbA1c (%)	18 months	F: Mean, 7.3 (SD, 1)	F: Mean, 7.3 (SD, 1)
Nuboer, 2008[32]	MDI + SMBG, 19	CSII + SMBG, 19	HbA1c (%)	7 months	B: Mean, 7.98 (SD, 0.57) F: Mean, 7.97 (SD, 0.78) F-B: -0.01	B: Mean, 7.66 (SD, 0.56) F: Mean, 7.49 (SD, 0.5) F-B: -0.17 G2-G1: -0.16
O'Connell, 2009[67]	SMBG	rtCGM, 25		3 months		Incidence 11 (44)
O'Connell, 2009[67]	SMBG, 29	rtCGM, 26	HbA1c (%)	3 months	Incidence 5 (17); P: 0.004 B: Mean, 7.5 (SD, 0.7) F: Mean, 7.8 (SD, 0.9) F-B: 0.3 G2-G1: Mean, -0.43 (95% CI, -0.75--0.19); P: 0.009	Incidence 14 (54) B: Mean, 7.3 (SD, 0.6) F: Mean, 7.1 (SD, 0.8) F-B: -0.2
O'Connell, 2009[67]	SMBG, 29	rtCGM, 26	Severe hypoglycemia (episode of hypoglycemia resulting in seizure or coma or requiring assistance or the use of glucagon or IV glucose for recovery)	3 months	Incidence 0 (0)	Incidence 0 (0)
Opipari-Arrigan, 2007[33]	MDI + rtCGM, 8	CSII + rtCGM, 6	HbA1c (%)	6 months	B: Mean, 7.98 (SD, 0.76) F: Mean, 8.24 (SD, 0.4); P: NS F-B: 0.26	B: Mean, 8.26 (SD, 1.37) F: Mean, 8.39 (SD, 0.83) F-B: 0.13 G2-G1: -0.13

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Opipari-Arrigan, 2007[33]	MDI + rtCGM, 8	CSII + rtCGM, 6	Hypoglycemia frequency (Daytime hypoglycemia: Frequency of low excursions <70 mg/dL)	6 months	B: Mean, 0.59 (SD, 0.32) F: Mean, 0.85 (SD, 0.58); P: NS F-B: 0.26	B: Mean, 1.53 (SD, 0.49) F: Mean, 0.89 (SD, 1.02) F-B: -0.64 G2-G1: -0.9
Opipari-Arrigan, 2007[33]	MDI + rtCGM, 8	CSII + rtCGM, 6	Severe hypoglycemia (Episodes)	6 months	Events 2; P: NS	Events 0
Peyrot, 2009[73]	MDI + SMBG, 14	CSII + rtCGM, 14	HbA1c (%)	16 weeks	B: 8.32 (1.05) F: Mean, 7.3 (SD, 0.92) F-B: Mean, -1	B: 8.87 (0.89) F: Mean, 7.16 (SD, 0.75) F-B: Mean, -1.7 G2-G1: Mean, -0.7; P: 0.071
Peyrot, 2009[73]	MDI + SMBG, 14	CSII + rtCGM, 14	Severe hypoglycemia (not further spec)	16 weeks	Events 3	Events 0
Peyrot, 2009[73]	MDI + SMBG, 14	CSII + rtCGM, 14	Weight gain (kg)	16 weeks	B: Mean, 82.61 (SD, 15.98) F: Mean, 84.56 (15.99) F-B: Mean, 2; P: NS vs. baseline G2-G1: Mean, 1.3	B: Mean, 77.69 (SD, 18.71) F: Mean, 78.37 (19.1) F-B: Mean, 0.7; P: NS vs. baseline G2-G1: P: 0.309
Pozzilli, 2003[43]	MDI, 12	CSII, 7	HbA1c (%)	2 years	B: Mean, 10.3 (SD, 3.4) F: Mean, 6.2 (SD, 0.3); P: NS F-B: -4.1	B: Mean, 11.7 (SD, 3.1) F: Mean, 6.3 (SD, 0.5) F-B: -5.4 G2-G1: -1.3
Pozzilli, 2003[43]	MDI, 12	CSII, 7	Severe hypoglycemia (not further spec)	2 years	Incidence 0 (0)	Incidence 0 (0)
Pozzilli, 2003[43]	MDI, 12	CSII, 7	Weight gain (kg: BMI (kg/m2))	2 years	B: Mean, 20.9 (SD, 3.8) F: Mean, 22; P: NS F-B: 1.1	B: Mean, 19.8 (SD, 3.5) F: Mean, 22.5 F-B: 2.7 G2-G1: 1.6
Raccah, 2009[65]	CSII + SMBG, 60	rtCGM, 55	HbA1c (%)	6 months	B: Mean, 9.28 (SD, 1.19) F-B: Mean, -0.57 (SD, 0.94); P: <0.001 vs. baseline	B: Mean, 9.11 (SD, 1.28) F-B: Mean, -0.81 (SD, 1.09); P: <0.001 vs. baseline G2-G1: -0.24; P: 0.087
Raccah, 2009[65]	CSII + SMBG, 54	rtCGM, 46	Hyperglycemia	6 months	F-B: Mean, -0.2 (SD, 0.7)	F-B: Mean, -0.2 (SD, 0.7) G2-G1: 0; P: >0.05

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Raccah, 2009[65]	CSII + SMBG, 54	rtCGM, 46	Hypoglycemia frequency (Moderate hypoglycemia: <70 mg/dl)	6 months	F-B: Mean, 0.1 (SD, 0.7)	F-B: Mean, 0.1 (SD, 0.9) G2-G1: 0; P: >0.05
Raccah, 2009[65]	CSII + SMBG, 54	rtCGM, 46	Ratio of basal to bolus insulin (Number of daily boluses)	6 months	F: Mean, 3.9 (SD, 1.4); P: 0.005	F: Mean, 4.7 (SD, 1.4)
Raccah, 2009[65]	CSII + SMBG, 54	rtCGM, 46	Ratio of basal to bolus insulin (Proportion of basal insulin)	6 months	F: Mean, 50.2 (SD, 15.8); P: >0.05	F: Mean, 46.2 (SD, 10)
Raccah, 2009[65]	CSII + SMBG, 60	rtCGM, 55	Severe hypoglycemia (not further spec)	6 months	Incidence 0 (0)	Incidence 1 (2)
Radermecker, 2010[63]	CSII + SMBG, 9	rtCGM, 9	HbA1c (%)	12 weeks	B: Mean, 7.9 (SD, 0.5) F: Mean, 8 (SD, 0.8) F-B: Mean, -0.09 (SD, 0.5; 95% CI, -0.48-0.3); P: 0.48 vs. baseline	B: Mean, 8.3 (SD, 0.7) F: Mean, 7.7 (SD, 0.6) F-B: Mean, 0.53 (SD, 0.66; 95% CI, 0.02-1); P: 0.049 vs. baseline G2-G1: 0.62
Radermecker, 2010[63]	CSII + SMBG, 9	rtCGM, 9	Hypoglycemia frequency (Mild hypoglycemia: <60 mg/dl)	12 weeks	B: Mean, 11.8 (SD, 7.1) F: Mean, 11.1 (SD, 4.5) F-B: Mean, 0.67 (SD, 6.9; 95% CI, -4.7-6); P: 0.55 vs. baseline	B: Mean, 13.9 (SD, 9.2) F: Mean, 7.6 (SD, 6.8) F-B: Mean, 6.2 (SD, 5.2; 95% CI, 2.2-10.2); P: 0.011 vs. baseline G2-G1: 5.53
Radermecker, 2010[63]	CSII + SMBG, 9	rtCGM, 9	Severe hypoglycemia (not further spec)	12 weeks	Incidence 0 (0)	Incidence 0 (0)
Raskin, 2003[57]	MDI, 61	CSII, 66	HbA1c (%)	24 weeks	B: Mean, 8 (SD, 1.1) F: Mean, 7.5 (SD, 1.17) F-B: Mean, -0.46 (SD, 0.89); P: <0.05 vs. baseline	B: Mean, 8.2 (SD, 1.4) F: Mean, 7.6 (SD, 1.22) F-B: Mean, -0.62 (SD, 1.11); P: <0.05 vs. baseline G2-G1: -0.16; P: NS
Raskin, 2003[57]	MDI, 61	CSII, 66	Hyperglycemia (Postprandial glucose: 90 min after breakfast from 8-pt SMBG)	24 weeks	F: Mean, 192 (SD, 65); P: 0.019	F: Mean, 167 (SD, 47.5)

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Raskin, 2003[57]	MDI, 61	CSII, 66	Hyperglycemia (Postprandial glucose: any BG>350 mg/dL (any time of day))	24 weeks	Incidence 11 (18) Events 26	Incidence 3 (5) Events 6
Raskin, 2003[57]	MDI, 61	CSII, 63	Hypoglycemia frequency (Mild hypoglycemia: symptoms, no assistance required, and BG <50 mg/dl)	24 weeks	Incidence 36 (59) Events 1.2 events / person-month; P: NR	Incidence 34 (54) Events 0.8 events / person-month
Raskin, 2003[57]	MDI, 59	CSII, 62	Hypoglycemia frequency (Nocturnal hypoglycemia: 12am-6am)	8-24 weeks	Incidence 13 (22); P: similarly low	Incidence 10 (16)
Raskin, 2003[57]	MDI, 61	CSII, 66	Severe hypoglycemia (BG<50,severe CNS dysfunction (necessitating outside assistance or parenteral glucose/glucagon))	24 weeks	Incidence 0 (0)	Incidence 0 (0)
Raskin, 2003[57]	MDI, 61	CSII, 66	Weight gain (kg)	24 weeks	B: Mean, 96.9 (SD, 17.9) F: Mean, 97.6 (SD, 19.2) F-B: 0.7	B: Mean, 96.4 (SD, 17) F: Mean, 98.1 (SD, 18.1) F-B: 1.7 G2-G1: 1; P: NS
Rigla, 2008[91]	SMBG, 10	rtCGM, 10	HbA1c (%)	4 weeks	B: Mean, 8.1 F: Mean, 7.8 F-B: Mean, 0.3	B: Mean, 8.1 (SD, 1.1) F: Mean, 7.3 (SD, 0.8) F-B: Mean, 0.8; P: 0.007 vs. baseline G2-G1: 0.5; P: 0.017
Schiaffini, 2005[39]	MDI, 16	CSII, 20	HbA1c (%)	12 months	B: Mean, 8.9 (SD, 1.7) F-B: Mean, 8.2 (SD, 0.9); P: NS vs. baseline	B: Mean, 8.5 (SD, 1.8) F-B: Mean, 7.6 (SD, 1.2); P: <0.05 vs. baseline G2-G1: -0.6
Schiaffini, 2005[39]	MDI, 16	CSII, 20	Severe hypoglycemia (Episodes/patient/ year)	12 months	B: Mean, 0.24 (SD, 0.44) F-B: Mean, 0.2 (SD, 0.4); P: NS vs. baseline	B: Mean, 0.25 (SD, 0.4) F-B: Mean, 0.2 (SD, 0.3); P: NS vs. baseline G2-G1: 0

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Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Schiaffini, 2007[34]	MDI, 17	CSII, 19	HbA1c (%)	24 months	B: Mean, 8.5 (SD, 0.9) F-B: Mean, 8.2 (SD, 1.4); P: NS vs. baseline	B: Mean, 8.3 (SD, 1.1) F-B: Mean, 7.6 (SD, 1.1); P: <0.05 vs. baseline G2-G1: -0.6
Schiaffini, 2007[34]	MDI, 17	CSII, 19	Severe hypoglycemia (Episodes/patient/ year)	24 months	B: Mean, 0.25 (SD, 0.3) F-B: Mean, 0.2 (SD, 0.2); P: NS vs. baseline	B: Mean, 0.3 (SD, 0.2) F-B: Mean, 0.3 (SD, 0.3); P: NS vs. baseline G2-G1: 0.1
Skogsberg, 2008[31]	MDI, 33	CSII, 34	HbA1c (%)	24 months	B: Mean, 8.4 (SE, 0.5) F: Mean, 6.7 (SE, 0.5); P: 0.66 F-B: -1.7	B: Mean, 8.2 (SE, 0.4) F: Mean, 6.5 (SE, 0.4) F-B: -1.7 G2-G1: 0
Skogsberg, 2008[31]	MDI, 33	CSII, 34	Hypoglycemia frequency (Daytime hypoglycemia: Episodes of perceived hypoglycemia)	24 months	G2-G1: Mean, 1.7 (SE, 0.4); P: 0.89	
Tamborlane, 2008[68] Ages 15-24	SMBG, 53	rtCGM, 57	HbA1c (%)	26 weeks	Incidence 9 (17); P: 0.8 B: Mean, 7.9 (SD, 0.8) F-B: Mean, -0.21 (SD, 0.61)	Incidence 8 (14) B: Mean, 8 (SD, 0.7) F-B: Mean, -0.18 (SD, 0.65) G2-G1: 0.03; P: 0.52
Tamborlane, 2008[68] Ages ≥25	SMBG, 46	rtCGM, 52	HbA1c (%)	26 weeks	Incidence 4 (9); P: 0.005 B: Mean, 7.6 (SD, 0.5) F-B: Mean, 0.02 (SD, 0.45)	Incidence 17 (33) B: Mean, 7.6 (SD, 0.5) F-B: Mean, -0.5 (SD, 0.56) G2-G1: -0.52; P: <0.001
Tamborlane, 2008[68] Ages 8-14	SMBG, 58	rtCGM, 56	HbA1c (%)	26 weeks	Incidence 7 (12); P: 0.01 B: Mean, 7.9 (SD, 0.6) F-B: Mean, -0.22 (SD, 0.54)	Incidence 15 (27) B: Mean, 8 (SD, 0.7) F-B: Mean, -0.37 (SD, 0.9) G2-G1: -0.15; P: 0.29
Tamborlane, 2008[68] Ages ≥25 years	SMBG, 46	rtCGM, 52	Hyperglycemia	26 weeks	B: 181 F: Mean, 161; P: <0.001 F-B: -20	B: 149 F: Mean, 101 F-B: -48 G2-G1: -28

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Tamborlane, 2008[68] Ages 8-14	SMBG, 58	rtCGM, 56	Hyperglycemia	26 weeks	B: Mean, 671 F: Mean, 635 F-B: -36	B: Mean, 745 F: Mean, 643 F-B: -102 G2-G1: -66
Tamborlane, 2008[68] Ages 8-14	SMBG, 58	rtCGM, 56	Hyperglycemia	26 weeks	B: Mean, 282 F: Mean, 268; P: 0.18 F-B: -14	B: Mean, 343 F: Mean, 242 F-B: -101 G2-G1: -87
Tamborlane, 2008[68] Ages 15-24	SMBG, 53	rtCGM, 57	Hyperglycemia	26 weeks	B: 265 F: 242; P: 0.44 F-B: -23	B: 271 F: 215 F-B: -56 G2-G1: -33
Tamborlane, 2008[68] Ages 15-24	SMBG, 53	rtCGM, 57	Hyperglycemia	26 weeks	B: Mean, 697 F: Mean, 761; P: 0.79 F-B: 64	B: Mean, 691 F: Mean, 761 F-B: 70 G2-G1: 6
Tamborlane, 2008[68] Ages 15-24	SMBG, 53	rtCGM, 57	Hyperglycemia	26 weeks	B: Mean, 641 F: Mean, 591; P: 0.85 F-B: -50	B: Mean, 650 F: Mean, 591 F-B: -59 G2-G1: -9
Tamborlane, 2008[68] Ages ≥25 years	SMBG, 46	rtCGM, 52	Hyperglycemia	26 weeks	B: Mean, 549 F: Mean, 519; P: 0.002 F-B: -30	B: Mean, 497 F: Mean, 394 F-B: -103 G2-G1: -73
Tamborlane, 2008[68] Ages 8-14	SMBG, 58	rtCGM, 56	Severe hypoglycemia (event that required assistance to administer oral carbohydrate, glucagon, or other resuscitative actions)	26 weeks	Incidence 6 (10); P: 0.74	Incidence 4 (7)

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Tamborlane, 2008[68] Ages 15-24	SMBG, 53	rtCGM, 57	Severe hypoglycemia (event that required assistance to administer oral carbohydrate, glucagon, or other resuscitative actions)	26 weeks	Incidence 5 (9); P: 0.48	Incidence 3 (5)
Tamborlane, 2008[68] Ages ≥25	SMBG, 46	rtCGM, 52	Severe hypoglycemia (event that required assistance to administer oral carbohydrate, glucagon, or other resuscitative actions)	26 weeks	Incidence 4 (9); P: 1	Incidence 5 (10)
Thomas, 2007[47]	MDI, 7	CSII, 7	HbA1c (%)	24 weeks	B: Mean, 8.6 (SD, 1.1) F: Mean, 7.6 (SD, 0.7) F-B: -1	B: Mean, 8.5 (SD, 1.9) F: Mean, 7.4 (SD, 1) F-B: -1.1 G2-G1: -0.1
Thomas, 2007[47]	MDI, 7	CSII, 7	Hyperglycemia (%)	24 weeks	B: Mean, 45 (SD, 15) F: 20 (17) F-B: -25	B: Mean, 32 (SD, 19) F: 31 (15) F-B: -1 G2-G1: 24
Thomas, 2007[47]	MDI, 7	CSII, 7	Hypoglycemia frequency (Mild hypoglycemia: symptomatic and confirmed by SMBG (<4 mmol/l))		Events 21 events / person-years	Events 40 events / person-years
Thomas, 2007[47]	MDI, 7	CSII, 7	Hypoglycemia frequency (Moderate hypoglycemia: Biochemical, <4.0 mmol/l)	24 weeks	B: Mean, 18 (SD, 13.7) F: Mean, 23 (SD, 16) F-B: 5	B: Mean, 23 (SD, 21) F: Mean, 12 (SD, 3.2) F-B: -11 G2-G1: -16

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Thomas, 2007[47]	MDI, 7	CSII, 7	Hypoglycemia frequency (Nocturnal hypoglycemia: NR)			Events 0
Thomas, 2007[47]	MDI, 7	CSII, 7	Severe hypoglycemia (biochemical, <2.5 mmol/l)	24 weeks	B: Mean, 6.7 (SD, 6) F: Mean, 8 (SD, 10); F-B: 1.3	B: Mean, 6.7 (SD, 7) F: Mean, 3 (SD, 3.6) F-B: -3.7 G2-G1: -5
Thomas, 2007[47]	MDI, 7	CSII, 7	Severe hypoglycemia (defined by ADA)	24 weeks	Incidence 2 (29) Events 0.6 events / person-years	Incidence 2 (29) Events 0.9 events / person-years
Thomas, 2007[47]	MDI, 7	CSII, 7	Weight gain (kg)	24 weeks	B: Mean, 78 (SD, 15.2) F: 77 (14.8); P: 0.88 vs. baseline0.94 vs. baseline F-B: -1	B: Mean, 72.5 (SD, 8.6) F: 72.9 (7.8) F-B: 0.4 G2-G1: 1.4
Tsui, 2001[52]	MDI, 14	CSII, 13	HbA1c (%)	9 months	B: Mean, 8.16 (SD, 0.7) F: Mean, 7.56; P: >0.10 F-B: -0.6	B: Mean, 7.73 (SD, 0.6) F: Mean, 7.38 F-B: -0.35 G2-G1: Mean, 0.25 (-0.19-0.68); P: >0.10
Tsui, 2001[52]	MDI, 14	CSII, 13	Hypoglycemia frequency (Mild hypoglycemia: symptoms relieved with glucose and/or BG <3 mmol/l)	9 months	Events 7.4 events / person-month over course of study; P: >0.10	Events 8 events / person-month over course of study Relative treatment effect (CSII-MDI)/MDI, 9; CI, -37 - 87
Tsui, 2001[52]	MDI, 14	CSII, 13	Severe hypoglycemia (events requiring assistance or resulting in a coma)	9 months	Events 4; P: >0.10	Events 6
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Birth weight (% LGA (>90th percentile))	36.4 weeks (3rd trimester)	Incidence 5 (22.7)	Incidence 9 (45)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Birth weight (% SGA)	36.4 weeks (3rd trimester)	Incidence 1 (4.5)	Incidence 1 (5)

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Birth weight (kg)	36.4 weeks (3rd trimester)	F: Mean, 3101.84 (SD, 699)	F: Mean, 3295.58 (SD, 747)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Cesarean delivery (Not further specified)	36.4 weeks (3rd trimester)	Incidence 21 (94)	Incidence 19 (95)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Frequency of neonatal hypoglycemia (transient hypoglycemia)	36.4 weeks (3rd trimester)	Incidence 3 (14)	Incidence 2 (10)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Gestational age (weeks)	36.4 weeks (3rd trimester)	F: Mean, 36.35 (SD, 2.3)	F: Mean, 36.38 (SD, 2.2)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	HbA1c (%)	36.4 weeks (3rd trimester)	F: Mean, 6.1 (SD, 1.1)	F: Mean, 6.3 (SD, 0.6)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	HbA1c (%)	6 weeks (1st trimester)	F: Mean, 7.4 (SD, 1.3)	F: Mean, 6.9 (SD, 0.7)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Major anomalies (congenital malformations, not further specified)	36.4 weeks (3rd trimester)	Incidence 0 (0)	Incidence 0 (0)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Minor anomalies (congenital malformations, not further specified)	36.4 weeks (3rd trimester)	Incidence 0 (0)	Incidence 0 (0)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Nephropathy (deterioration of condition)	36.4 weeks (3rd trimester)	Incidence 0 (0)	Incidence 0 (0)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	NICU admission (not further specified)	36.4 weeks (3rd trimester)	Incidence 2 (9)	Incidence 1 (5)
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Retinopathy (deterioration of condition)	36.4 weeks (3rd trimester)	Incidence 0 (0)	Incidence 0 (0)

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Severe hypoglycemia (hypoglycemic emergency requiring assistance)	36.4 weeks (3rd trimester)	Incidence 1 (5) Events 1	Incidence 1 (5) Events 1
Volpe, 2010[59]	MDI, 22	CSII + SMBG, 20	Weight gain (kg)	36.4 weeks (3rd trimester)	F-B: Mean, 11.5 (SD, 3.7)	F-B: Mean, 13.4 (SD, 5.4) G2-G1: 1.9
Wainstein, 2005[58]	MDI, 20	CSII, 20	HbA1c (%)	18 weeks	B: Mean, 0.4 (SD, 1.3)	B: Mean, -0.8 (SD, 1.5) G2-G1: P: 0.007
Wainstein, 2005[58] T2DM	MDI, 20	CSII, 20	HbA1c (%)	48 weeks	B: Mean, -0.4 (SD, 1.3)	B: Mean, -0.8 (SD, 1.5) G2-G1: P: 0.4
Wainstein, 2005[58] T2DM	MDI, 20	CSII, 20	HbA1c (%)	18 weeks	F-B: Mean, 1.5 (SD, 0.8)	F-B: Mean, 0.8 (SD, 1.5); P: 0.1 vs. baseline G2-G1: -0.7
Wainstein, 2005[58]	MDI, 20	CSII, 20	HbA1c (%)	48 weeks	F: Mean, 8.8 (SD, 1.5)	F: Mean, 8.8 (SD, 1.4)
Wainstein, 2005[58]	MDI, 20	CSII, 20	HbA1c (%)	18 weeks	F: Mean, 8.4 (SD, 1.3)	F: Mean, 7.9 (SD, 1)
Wainstein, 2005[58]	MDI	CSII	Hypoglycemia frequency (Mild hypoglycemia: BG<3 mmol/l and not requiring assistance)		“Did not vary by treatment period”	Daily insulin requirement
Wainstein, 2005[58]	MDI, 40	CSII, 40	Severe hypoglycemia (major'-intervention from others)		Events 2	Events 3
Weintrob, 2003[42]	MDI, 23	CSII, 23	HbA1c (%)	3.5 months	B: Mean, 8.3 (SD, 0.7) F: Mean, 8.2 (SD, 0.8) F-B: Mean, -0.23 (SD, 1)	B: Mean, 8 (SD, 1.1) F: Mean, 7.9 (SD, 0.7) F-B: Mean, 0.03 (SD, 1) G2-G1: 0.26
Weintrob, 2003[42]	MDI, 23	CSII, 23	Hyperglycemia	3.5 months	Events 6.7 events / patient; P: <0.05	Events 7.9 events / patient
Weintrob, 2003[42]	MDI, 23	CSII, 23	Hypoglycemia frequency (Mild hypoglycemia: <3.8 mmol)	3.5 months	Events 22 events / patient; P: <0.05	Events 19.8 events / patient

Table 4. Outcomes of studies comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Group 1, N	Group 2, N	Outcome (definition)	Timepoint	Results, Group1	Results, Group2
Weintrob, 2003[42]	MDI, 23	CSII, 23	Severe hypoglycemia (Any hypoglycemic event requiring assistance from another person or resulting in a seizure/coma)	3.5 months	Events 3; P: <0.05	Events 1
Weintrob, 2003[42]	MDI, 23	CSII, 23	Weight gain (BMI-SDS)	3.5 months	B: Mean, 0.29 (SD, 0.81) F: Mean, 0.37 (SD, 0.85) F-B: 0.08	B: Mean, 0.4 (SD, 0.79) F: Mean, 0.35 (SD, 0.83) F-B: -0.05 G2-G1: -0.13; P: 0.012
Yoo, 2008[92]	SMBG, 28	rtCGM, 29	HbA1c (%)	3 months	B: Mean, 8.7 (SD, 0.7) F: Mean, 8.3 (SD, 1.1) F-B: -0.4; P: 0.01 vs. baseline	B: Mean, 9.1 (SD, 1) F: Mean, 8 (SD, 1.2) F-B: -1.1; P: <0.001 vs. baseline G2-G1: -0.7; P: 0.004
Yoo, 2008[92]	SMBG, 28	rtCGM, 29	Hyperglycemia (Fasting glucose (mmol/L))	3 months	B: Mean, 6.5 (SD, 1.3) F: Mean, 7.2 (SD, 2.2) F-B: 0.7; P: >0.05 vs. baseline	B: Mean, 6.3 (SD, 1.3) F: Mean, 6.5 (SD, 1.2) F-B: 0.2; P: >0.05 vs. baseline G2-G1: -0.5; P: 0.48
Yoo, 2008[92]	SMBG, 28	rtCGM, 29	Hyperglycemia (Postprandial glucose (mg/dL))	3 months	B: Mean, 11.5 (SD, 3.6) F: Mean, 10.9 (SD, 4.1) F-B: -0.6; P: >0.05 vs. baseline	B: Mean, 11.3 (SD, 2.8) F: Mean, 10 (SD, 2.5) F-B: -1.3; P: <0.05 vs. baseline G2-G1: -0.7; P: 0.48
Yoo, 2008[92]	SMBG, 28	rtCGM, 29	Severe hypoglycemia (not further spec)	3 months	Incidence 0 (0)	Incidence 0 (0)
Yoo, 2008[92]	SMBG, 28	rtCGM, 29	Weight gain (kg)	3 months	B: Mean, 65.7 (SD, 12.3) F: Mean, 64.3 (SD, 12.5) F-B: -1.4; P: >0.05 vs. baseline	B: Mean, 63.3 (SD, 12.4) F: Mean, 61.1 (SD, 12.2) F-B: -2.2; P: <0.05 vs. baseline G2-G1: -0.8; P: 0.43

ADA = American Diabetes Association; B = baseline results; BG = blood glucose; BMI-SDS = body mass index-standard deviation score; CI = confidence interval; CNS = central nervous system; CSII = continuous subcutaneous insulin infusion; DCCT = Diabetes Control and Complications Trial; F = final results; F-B = change score results; G2-G1 = between-group difference results; HbA1c = hemoglobin A1c; IV = intravenous; JDRF = Juvenile Diabetes Research Foundation; kg = kilograms; kg/m2 = kilograms per meter squared; LGA = large for gestational age; LOC = loss of consciousness; MDI = multiple daily injections; mg/dL = milligrams per deciliter; mmol/L = millimole per liter; NICU = neonatal intensive care unit; NR = not reported; NS = not significant; PG = plasma glucose; rtCGM = real-time continuous glucose monitor; SD = standard deviation; SGA = small for gestational age; SMBG = self monitoring of blood glucose

Table 5. Study quality of randomized controlled trials comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Sequence Generation	Allocation concealment	Blinding, Personnel, Outcome	Incomplete Outcome Data	Pharmaceutical support	Company involvement	Overall quality*
Bergenstal, 2010[72]	No	No	No	Yes	Yes	Unable to determine	Poor
Bolli, 2009[45]	Yes	Yes	No	Yes	Yes	Unable to determine	Fair
Bolli, 2009[45]	Unclear	Unclear	No	No	Yes	Yes	Poor
Bruttomesso, 2008[46]	Yes	Unclear	Unclear	No	Yes	Yes	Fair
Bruttomesso, 2008[46]	Unclear	Yes	No	Yes	Yes	Yes	Poor
Cohen, 2003[41]	Unclear	Unclear	No	Unclear	Yes	Unable to determine	Poor
Cohen, 2003[41]	Unclear	Unclear	No	Unclear	Yes	Unable to determine	Poor
Deiss, 2006[70]	Unclear	Unclear	Unclear	Unclear	Yes	Unable to determine	Poor
Deiss, 2006[70]	Unclear	Unclear	Yes	Yes	Yes	Unable to determine	Good
Derosa, 2009[56]	Unclear	Unclear	Unclear	No	Unable to determine		Fair
DeVries, 2002[51]	Yes	Yes	No	No	Yes	Unable to determine	Fair
DeVries, 2002[51]	Yes	Yes	No	Yes	Yes	Unable to determine	Fair
Doyle, 2004[40]	Yes	Yes	No	Yes	Yes	No	Good
Doyle, 2004[40]	Yes	Unclear	Unclear	Yes	Yes	Unable to determine	Good
Garcia-Garcia, 2007[35]	Unclear	Unclear	Unclear	Unclear	Unable to determine		Poor
Garcia-Garcia, 2007[35]	Unclear	Unclear	Unclear	Unclear	No		Poor
Hanaire-Broutin, 2000[53]	Yes	No	No		Yes	Unable to determine	Fair
Hanaire-Broutin, 2000[53]	Unclear	Unclear	No	Yes	Yes	Unable to determine	Good
Herman, 2005[55]	Unclear	Yes	Unclear	Unclear	Yes	Unable to determine	Fair
Herman, 2005[55]	Yes	No	No	No	Yes	Unable to	Fair

Table 5. Study quality of randomized controlled trials comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Sequence Generation	Allocation concealment	Blinding, Personnel, Outcome	Incomplete Outcome Data	Pharmaceutical support	Company involvement	Overall quality*
						determine	
Hirsch, 2005[49]	Yes	No	No	Yes	Yes		Fair
Hirsch, 2005[49]	Unclear	Unclear	Unclear	No	Yes	Yes	Fair
Hirsch, 2008[69]	Unclear	Unclear	No	Yes	Yes	Yes	Good
Hirsch, 2008[69]	Unclear	Unclear	Yes	Yes	Yes	Unable to determine	Good
Hoogma, 2006[48]	Unclear	Unclear	No	No	Yes	Unable to determine	Poor
Hoogma, 2006[48]	Yes	No	No	Yes	Yes		Fair
JDRF CGM Study Group, 2009[66]	Yes	Unclear	No	Yes	Yes	Unable to determine	Good
Kordonouri, 2010[64]	Yes	Yes	No	Yes	Yes	Unable to determine	Good
Kordonouri, 2010[64]	Unclear	Yes	Yes	Yes	Yes	Unable to determine	Good
Lee, 2007[74]	Unclear	Unclear	No	No	Unable to determine		Fair
Lee, 2007[74]	Unclear	Unclear	Unclear	Unclear	Unable to determine	Unable to determine	Fair
Lepore, 2003[50]	Unclear	Unclear	No	Unclear	Unable to determine	Unable to determine	Poor
Lepore, 2003[50]	Unclear	Unclear	Unclear	Unclear	Unable to determine		Fair
Nuboer, 2008[32]	Unclear	Unclear	No	Unclear	No	Unable to determine	Poor
Nuboer, 2008[32]	Unclear	Unclear	Unclear	Yes	No		Fair
O'Connell, 2009[67]	Yes	Yes	No	Yes	Yes	No	Good
O'Connell, 2009[67]	Yes	Yes	No	No	Yes	Unable to determine	Good
Opipari-Arrigan, 2007[33]	Unclear	Unclear	No	Unclear	No	Unable to determine	Poor
Opipari-Arrigan, 2007[33]	Unclear	Unclear	Unclear	Unclear	Unable to determine		Poor
Peyrot, 2009[73]	Unclear	Unclear	Unclear	Yes	Yes	No	Poor

Table 5. Study quality of randomized controlled trials comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Sequence Generation	Allocation concealment	Blinding, Personnel, Outcome	Incomplete Outcome Data	Pharmaceutical support	Company involvement	Overall quality*
Peyrot, 2009[73]	Unclear	No		Yes	Yes	No	Poor
Pozzilli, 2003[43]	Unclear	No	No	Unclear	Yes	Unable to determine	Fair
Pozzilli, 2003[43]	Unclear	No	No	No	Yes	Unable to determine	Fair
Raccah, 2009[65]	Unclear	Unclear	No	No	Yes	Unable to determine	Fair
Radermecker, 2010[63]	Unclear	Unclear	No	Yes	No	No	Fair
Radermecker, 2010[63]	Unclear	Unclear	No	No	No	Unable to determine	Fair
Raskin, 2003[57]	Yes	Unclear	Unclear	No	Yes	Unable to determine	Poor
Raskin, 2003[57]	Yes	Yes	No	Yes	Yes	Unable to determine	
Rigla, 2008[91]	Unclear	Unclear	No	Yes	Yes	No	Poor
Rigla, 2008[91]	Unclear	Unclear	Yes	Yes	Yes	Unable to determine	Good
Schiaffini, 2007[34]	Unclear	Unclear	Unclear	Unclear	No		Poor
Schiaffini, 2007[34]	Unclear	Unclear	No	Unclear	No		Poor
Skogsberg, 2008[31]	Unclear	Unclear	Unclear	Unclear	Unable to determine		Fair
Skogsberg, 2008[31]	Unclear	Unclear	No	Unclear	Yes	Unable to determine	Fair
Tamborlane, 2008[68]	Yes	Unclear	No	Unclear	Yes	Unable to determine	Fair
Tamborlane, 2008[68]	Unclear	Unclear	No	Yes	No	Unable to determine	Fair
Thomas, 2007[47]	Unclear	Unclear	Unclear	Unclear	Yes	No	Fair
Thomas, 2007[47]	Unclear	Unclear	No	Yes	Yes	No	Fair
Tsui, 2001[52]	Yes		Unclear	Yes	Yes	Unable to determine	Good
Tsui, 2001[52]	Yes	Yes	No	Unclear	Yes	Unable to determine	Fair
Wainstein, 2005[58]	Unclear	Unclear	Unclear	No	Unable to determine		Fair

Table 5. Study quality of randomized controlled trials comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Sequence Generation	Allocation concealment	Blinding, Personnel, Outcome	Incomplete Outcome Data	Pharmaceutical support	Company involvement	Overall quality*
Wainstein, 2005[58]	Unclear	No	No	Yes	Unable to determine		Fair
Weintrob, 2003[42]	Unclear	Unclear	No	Yes	Yes	Unable to determine	Fair
Yoo, 2008[92]	Yes	Yes	Yes	Yes	Yes	Unable to determine	Good
Yoo, 2008[92]	Yes	Yes	No	No	Yes	Unable to determine	Fair

CGM = continuous glucose monitor; JDRF = Juvenile Diabetes Research Foundation

* Overall quality was rated as:

- Good (low risk of bias). These studies had the least bias, and the results were considered valid. These studies adhered to the commonly held concepts of high quality, including the following: a clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; a low dropout rate; and clear reporting of dropouts.
- Fair. These studies were susceptible to some bias, but not enough to invalidate the results. They did not meet all the criteria required for a rating of good quality because they had some deficiencies, but no flaw was likely to cause major bias. The study may have been missing information, making it difficult to assess limitations and potential problems.
- Poor (high risk of bias). These studies had significant flaws that might have invalidated the results. They had serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.[24]

Table 5. Study quality of randomized controlled trials comparing insulin delivery or glucose monitoring methods for diabetes mellitus

Author, year	Setting or population described	Eligibility criteria described	Key characteristics described	Patients recruited from same population	Adjusted or stratified results	Followup loss described	Percent lost followup	Overall quality*
Volpe, 2010[59]	Yes (incomplete)	Yes	Some	Yes	No	No	NR	Fair
Volpe, 2010[59]	Yes (incomplete)	Yes	Some	Yes	No	No	NR	Fair
Cypryk, 2008[60]	Yes (incomplete)	Yes	Some	Yes	Yes	No	NR	Fair
Cypryk, 2008[60]	Yes (incomplete)	Yes	Some	Yes	No	No	NR	Fair
Kernaghan, 2008[61]	Yes (incomplete)	Yes	Some	Yes	No	No	NR	Fair
Kernaghan, 2008[61]	No	Yes	Some	Yes	No	No	NR	Fair
Garcia-Garcia, 2007[35]	Yes (incomplete)	Yes	Yes with description	Yes	Yes	No	NR	Fair
Bin-Abbas, 2006[36]	No	No	Some	Unclear	No	Unclear	NR	Poor
Bin-Abbas, 2006[36]	No	No	Some	Yes	No	Unclear	NR	Poor
Kordonouri, 2006[37]	Yes (incomplete)	Yes	Some	No	Yes	Unclear	NR	Fair
Kordonouri, 2006[37]	Yes (incomplete)	Yes	Some	No	Yes	Unclear	NR	Fair
Minkina-Pedras, 2005[38]	Yes (incomplete)	Yes	Some	Yes	Yes	Yes	<10%	Fair
Hieronimus, 2005[62]	Yes (incomplete)	No	Yes with description	Unclear	No	Unclear	NR	Fair
Hieronimus, 2005[62]	Yes (incomplete)	No	Yes with description	Yes	No	NA	<10%	Fair
Schiaffini, 2005[39]	Yes (incomplete)	Yes	Yes with description	Yes	No	NA	NR	Fair

* Overall quality was rated as:

- Good (low risk of bias). These studies had the least bias, and the results were considered valid. These studies adhered to the commonly held concepts of high quality, including the following: a clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; a low dropout rate; and clear reporting of dropouts.
- Fair. These studies were susceptible to some bias, but not enough to invalidate the results. They did not meet all the criteria required for a rating of good quality because they had some deficiencies, but no flaw was likely to cause major bias. The study may have been missing information, making it difficult to assess limitations and potential problems.
- Poor (high risk of bias). These studies had significant flaws that might have invalidated the results. They had serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.[24]