



Effective Health Care

Treatment of Lymphocytic Colitis

Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Treatment of lymphocytic colitis is not feasible for a full systematic review due to the limited data available for a review at this time.
- Treatment of lymphocytic colitis could potentially be considered for new research in comparative effectiveness.

Topic Description

Nominator: Individual

Nomination Summary: The nominator questions what treatments are effective for lymphocytic colitis.

Staff-Generated PICO

Population(s): Patients diagnosed with lymphocytic colitis

Intervention(s): Dietary modification, antidiarrheals, bulking agents, bile acid binding agents, spasmolytics, antibiotics, bismuth subsalicylate, sulfasalazine/other 5-ASA products, traditional corticosteroids, budesonide, azathioprine/6-mercaptopurine, cyclosporine, and surgery

Comparator(s): Comparative effectiveness of interventions listed above

Outcome(s): Decreased stool frequency and/or stool weight, quality of life, adverse events

Key Questions from Nominator: None

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- Only two published trials were identified that address the effectiveness or comparative effectiveness of treatments for lymphocytic colitis. Both of these trials included fewer than 50 patients with lymphocytic colitis. There are two ongoing trials on the treatment of LC; however, even with the addition of data from these trials, there would still likely be insufficient information for the completion of a systematic

review of the evidence given that these trials address different combinations of interventions and include small sample sizes.

Published trials:

- Calabrese C, Fabbri A, Areni A, et al. Mesalazine with or without cholestyramine in the treatment of microscopic colitis: randomized controlled trial. *J Gastroenterol Hepatol* 2007 Jun;22(6):809-14. PMID: 17565633.
- Miehke S, Madisch A, Karimi D, et al. Budesonide is effective in treating lymphocytic colitis: a randomized double-blind placebo-controlled study. *Gastroenterology* 2009 Jun;136(7):2092-100. PMID: 19303012.

Ongoing clinical trials:

- NCT01209208- Budesonide Versus Mesalazine Versus Placebo in Lymphocytic Colitis. <http://clinicaltrials.gov/ct2/show/NCT01209208?term=NCT01209208&rank=1>
- NCT00184171- Treatment of Microscopic Colitis. <http://clinicaltrials.gov/ct2/show/NCT00184171?term=NCT00184171&rank=1>

Importance of New Research

- Given the limited evidence identified related to the treatment of lymphocytic colitis and the lack of information regarding the long-term effectiveness of treatments, this topic appears to be an important area for new research.

Research Gaps

- Authors of reviews have noted that while therapies for lymphocytic colitis appear to be effective and well tolerated, the existing studies are small and lack long-term follow-up data. Two ongoing studies are currently addressing the use of budesonide versus mesalazine and budesonide versus bismuth with fiber. However, both of these ongoing studies include small study populations.
- The 2009 review by Chande and colleagues at the Cochrane Inflammatory Bowel Disease and Functional Bowel Disorders Review Group aimed to address the effectiveness of any therapy for clinically active lymphocytic colitis and collagenous colitis. Only one published trial and two meeting abstracts addressing lymphocytic colitis were identified for inclusion in the review. No trials were identified that assessed the maintenance of response in patients with lymphocytic colitis.
 - Chande N, Macdonald JK, McDonald JW. Interventions for treating microscopic colitis: a Cochrane Inflammatory Bowel Disease and Functional Bowel Disorders Review Group systematic review of randomized trials. *American Journal of Gastroenterology* 2009;104(1):235-41. PMID: 19098875.