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## A meta-analysis of the benefit of probiotics in maintaining remission of human ulcerative colitis: evidence for prevention of disease relapse and maintenance of remission

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### CRD summary

This review concluded that probiotics were effective in maintaining remission in patients with ulcerative colitis and their effect in preventing relapse was comparable with mesalazine. Language, publication and reviewer bias were possible and trials of unknown quality may have been pooled inappropriately, so the authors' conclusions should be viewed with caution.

### Authors' objectives

To evaluate the efficacy of probiotics in preventing relapse in patients with ulcerative colitis and compare probiotics with mesalazine.

### Searching

PubMed, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) were searched for English-language articles. Search dates spanned 1966 to January 2008. Search terms were reported. Reference lists were searched for additional articles.

### Study selection

Controlled trials that investigated the efficacy of probiotics in maintaining remission in patients with ulcerative colitis were eligible for inclusion. Relapse was the main outcome of interest (defined as the appearance of symptoms and/or signs that needed additional medical treatment or any increase in colitis activity index to more than 4 points).

Included studies either compared probiotics with placebo or compared probiotics with mesalazine (doses ranged from 1,200mg/day to 2,400mg/day). Mean ages of patients ranged from 33.5 to 43.5 year (where reported). Probiotics used were bifidobacteria, bifid triple viable capsule, *Escherichia coli* preparation and *Lactobacillus* GG. A variety of bacteria was named in the probiotics. Doses ranged from  $1 \times 10^{10}$  to  $5 \times 10^{10}$  viable bacteria per day. Treatment duration varied from two to 12 months. Where reported, patients were treated with various drugs before the study (including steroids, salicylates).

Three reviewers independently selected studies for inclusion.

### Assessment of study quality

The authors did not state that validity was assessed.

### Data extraction

Data were extracted into 2x2 tables. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. The authors did not state how many reviewers extracted data.

### Methods of synthesis

Weighted odds ratios and 95% CIs were pooled using the Mantel-Haenszel fixed-effect model. Statistical heterogeneity was assessed using the Breslow-Day test and a L'Abbe plot. Publication bias was examined using a funnel plot.

### Results of the review

Six randomised controlled trials (RCTs) were included (n=588).

Placebo was associated with a significantly greater relapse rate than probiotics (OR 0.0269, 95% CI 0.0049 to 0.1478,  $p < 0.0001$ ; two RCTs, n=55). There was no significant difference in relapse rate with mesalazine compared with probiotics (four RCTs, n=533). No significant heterogeneity was detected in either analysis.

### Authors' conclusions

Probiotics were effective in maintaining remission; their effect in preventing relapse was comparable with mesalazine.

### CRD commentary

The research question was supported by inclusion criteria for participants, intervention, outcomes and study design. Searches were restricted to English-language articles, so language bias could not be ruled out. The authors did not report any attempts to identify unpublished studies, but publication bias was not indicated by the funnel plot. Multiple reviewers performed study selection; the authors did not report whether similar steps to reduce reviewer error and bias were taken during data extraction. Methodological quality of included studies was not assessed, so their reliability was not known. Statistical heterogeneity was assessed. A range of doses and probiotics were used and there was insufficient information about ulcerative colitis severity and concomitant treatments to determine whether studies were sufficiently similar to justify pooling data. As language and reviewer bias were possible and trials of unknown quality may have been pooled inappropriately, the authors' conclusions should be viewed with caution.

### Implications of the review for practice and research

**Practice:** The authors stated that probiotics seemed to be an appropriate alternative to mesalazine or a supplement in maintaining remission in patients with ulcerative colitis.

**Research:** The authors stated that the role of probiotics in maintenance treatment of ulcerative colitis needed to be assessed further by larger controlled trials.

### Funding

None stated.

### Bibliographic details

Rahimi R, Nikfar S, Rezaie A, Abdollahi M. A meta-analysis of the benefit of probiotics in maintaining remission of human ulcerative colitis: evidence for prevention of disease relapse and maintenance of remission. Archives of Medical Science 2008; 4(2): 185-190

### Original Paper URL

[http://www.termedia.pl/magazine.php?magazine\\_id=19&article\\_id=10671&magazine\\_subpage=ABSTRACT](http://www.termedia.pl/magazine.php?magazine_id=19&article_id=10671&magazine_subpage=ABSTRACT)

### Indexing Status

Subject indexing assigned by CRD

### MeSH

Bifidobacterium; Clostridium butyricum; Colitis, Ulcerative; Escherichia coli; Humans; Lactobacillus; Probiotics; Recurrence

### AccessionNumber

12009100144

### Date bibliographic record published

07/04/2009

### Date abstract record published

17/02/2010

### Record Status

This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.

