CRD summary
This review examined the effectiveness of probiotics and anti-inflammatory drugs in patients with ulcerative colitis and concluded that the two treatment options appeared to have similar effectiveness and safety. The authors’ conclusions were cautious, due to variation between studies, and are likely to be reliable.

Authors' objectives
To compare the effect of probiotics to anti-inflammatory treatment or placebo in the remission of ulcerative colitis.

Searching
PubMed, ScienceDirect, Cochrane (exact database not stated) and Google Scholar databases were searched from inception until October 2007 without language restrictions; search terms were reported. The metaRegister of Controlled Trials and National Institutes of Health online clinical trial registers were searched. Reference lists, authors, associated diseases and meeting abstracts were handsearched.

Study selection
Randomised controlled trials (RCTs) of probiotic use for the induction of remission and/or maintenance of remission in participants with ulcerative colitis were eligible for inclusion in the review.

A range of probiotics was used in the included studies, with E. coli and Bifidobacteria being the most common (three studies each). Most studies used mesalazine or placebo as a comparator. Treatment duration ranged from four weeks to 12 months. A broad range of doses was used. Participants in included studies had a range of severities of ulcerative colitis. The most common outcome measures were clinical improvement based on a clinical activity index (CAI) score and adverse effects.

Two reviewers selected studies for inclusion. Disagreements were by a third reviewer.

Assessment of study quality
Studies were evaluated on the following items: inclusion and exclusion criteria; co-treatment/concomitant medication use; and outcome measurement.

The authors did not state how the validity assessment was performed.

Data extraction
Data on the number of outcomes in the intervention and comparator groups were extracted and relative risks with 95% confidence intervals (CIs) were calculated.

The authors stated neither how the data were extracted for the review nor how many reviewers performed the data extraction.

Methods of synthesis
Meta-analyses examining pooled relative risks for various outcomes (including adverse effects) were performed using a random-effects model. It was unclear as to whether (and how) studies were weighted. Heterogeneity was investigated using the Cochran Q test.

Results of the review
Nine RCTs (n=972) were included in the review. Sample size ranged from 18 to 327 participants. For the validity assessment, only four studies fulfilled all three items.
Efficacy:

A combined assessment of induction and maintenance of remission yielded no statistically significant difference between probiotic and control groups (relative risk 1.51, 95% CI: 0.79 to 2.87, p=0.21; nine trials), but significant heterogeneity was found (Q=28.6). Pooling of the three trials that examined induction of remission showed a statistically significant difference favouring probiotic treatment (relative risk 2.27, 95% CI: 1.00 to 5.14, p=0.049). Pooling of the six trials that examined maintenance of remission showed no statistically significant difference (relative risk 1.37, 95% CI: 0.62 to 3.04, p=0.44), but statistically significant heterogeneity was seen (Q=24.3). Pooling of the five trials that compared probiotics with anti-inflammatory drugs showed no statistically significant difference (relative risk 0.95, 95% CI: 0.58 to 1.55, p=0.84) and no heterogeneity (Q=9.6). Pooling results of the four trials that compared probiotics with placebo revealed statistically significant higher remission for participants receiving probiotics (relative risk 7.32, 95% CI: 1.37 to 39.13, p=0.02), with significant heterogeneity (Q=7.42). Further results were reported.

Adverse effects:

Seven trials had data on adverse effects. No statistically significant difference was seen (relative risk 1.17, 95% CI: 0.81 to 1.70, p=0.40) and no significant heterogeneity was found (Q=5.47). Analyses for subgroups of studies showed no statistically significant differences.

Authors' conclusions

Probiotics and anti-inflammatory drugs appeared to have similar efficacy and safety for the treatment of ulcerative colitis, based on limited evidence with wide clinical and methodological variation.

CRD commentary

The review addressed a clear question and was supported by appropriate inclusion criteria. Attempts to identify all relevant studies in any language were undertaken by searching electronic databases and several other sources. Although the authors reported using methods to minimise the risk of errors and bias for selecting studies, they provided no such details on the data extraction and validity assessment processes. Sufficient study details were provided (although a description of the types of adverse effects found would have been useful), but the assessment of study validity was rather basic in its scope and was used little in interpreting the results of the review. Although appropriate methods were identified to pool results and investigate statistical heterogeneity, the synthesis used was sometimes difficult to follow and interpret; both relative risks and odds ratios were reported, but with conflicting details in text and tables. The authors did, however, acknowledge the considerable clinical and methodological heterogeneity between studies. Their suitably cautious conclusions are likely to be reliable.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that further clinical trials were needed to establish whether probiotics can reduce the relapse of ulcerative colitis and also to establish whether probiotics were safer and more effective than anti-inflammatory drugs. The authors also stated that continued investigation into the ways by which appropriate bacteria may prevent or improve the chronic inflammatory state was necessary.

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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.