CRD summary
This review assessed the efficacy of infliximab compared with placebo for the treatment of ulcerative colitis. The authors concluded that infliximab was effective in inducing clinical response and remission when given in conjunction with corticosteroids. The conclusion reflects the evidence of the included studies, but its reliability is uncertain in the absence of an assessment of the validity of the studies.

Authors' objectives
To assess the efficacy of infliximab in the treatment of ulcerative colitis.

Searching
PubMed and EMBASE were searched from 1966 to 2006; the search terms were reported. The reference lists of retrieved articles were also checked.

Study selection
Randomised controlled trials (RCTs) that compared infliximab with placebo were eligible for inclusion. In the included studies, infliximab was given at doses of 5, 10 or 20 mg/kg between one and three times over a 7-week period. The included studies also employed one or more of the following concomitant therapies: glucocorticoids, 5-aminosalicylates, immunosuppressants, azathioprine, antibiotics. Studies of patients with active ulcerative colitis of any age and both sexes were eligible for inclusion. The mean age of the patients in the included studies ranged from 36.9 to 41.9 years, and the majority were male. Inclusion criteria for the outcomes were not stated, but the primary outcome of the review was clinical improvement. The included studies evaluated clinical response using the Mayo score or the Truelove and Witt's score, and clinical remission using the ulcerative colitis symptom score, the Baron score, the Seo index or the Mayo score. Time to clinical response was also assessed in the review.

Three reviewers independently assessed studies for inclusion. Any differences were resolved through consensus.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Data on clinical response and clinical remission, including the definition employed for these outcomes, were extracted. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated.

The data were extracted into 2x2 tables. Three reviewers independently extracted the data and any differences were resolved through consensus.

Methods of synthesis
The ORs were pooled in a meta-analysis using the random-effects model of DerSimonian and Laird. Statistical heterogeneity between the trials was assessed using Breslow-Day tests for heterogeneity.

Results of the review
Five RCTs (n=827) (from four publications) were included in the review.

Clinical remission (4 RCTs) showed a significant benefit for infliximab over placebo; the pooled OR was 3.24 (95% CI: 1.6, 6.57, p=0.0011).
Clinical response (3 RCTs) also showed a significant benefit for infliximab over placebo; the pooled OR was 3.93 (95% CI: 2.84, 5.45, p=0.0001).

No statistically significant heterogeneity was detected for either outcome.

**Authors' conclusions**

Infliximab is effective in inducing response and remission in patients with ulcerative colitis when administered in conjunction with corticosteroids.

**CRD commentary**

The review question and the inclusion criteria were clear. The authors searched two relevant databases, but did not state that they sought unpublished studies. This increases the possibility that some relevant studies were not included in the review. The authors used appropriate methods to select studies for the review and to extract data from the included studies, thereby minimising the risk of bias and error. They did not state that they assessed validity, which makes it difficult to assess the evidence on which the conclusions were based, and hence their reliability. The decision to employ meta-analysis appears appropriate as, although there was some clinical heterogeneity, statistical heterogeneity was not found to be significant. However, it does appear that different outcome scales were pooled, which is not always appropriate. In the absence of an assessment of the validity of the included studies, it is difficult to confirm the reliability of the conclusions.

**Implications of the review for practice and research**

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

Research: The authors stated that further trials are required to confirm the efficacy of TNF-α antibodies administered without corticosteroids.

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**Bibliographic details**

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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.