Background Based on several experimental results and on a preliminary study, a trial was undertaken to assess the efficacy of adalimumab, a tumour necrosis factor (TNF) α inhibitor, in patients with radicular pain due to lumbar disc herniation.

Methods A multicentre randomised double-blind controlled trial was conducted between May 2005 and December 2007 in Switzerland. Patients with acute (<12 weeks) and severe (Oswestry disability index >50) radicular leg pain and imaging-confirmed lumbar disc herniation were randomised to receive as adjuvant therapy either two subcutaneous injections of adalimumab (40 mg) at 7-day interval or matching placebo. The primary outcome was leg pain, which was recorded every day for 10 days and at 6 weeks and 6 months based on a visual analogue scale (0–100).

Results Of the 265 patients screened, 61 were enrolled (adalimumab=1) and 4 were lost to follow-up. Over time, leg pain decreased to a significantly greater extent in the adalimumab group than in the placebo group ($p<0.001$), but the effect size was relatively small (13.8 (95% CI –11.5 to 39.0) at 6 months). In addition, in the adalimumab group twice as many patients fulfilled the criteria for ‘responders’ and for ‘low residual disease impact’ ($p<0.05$) and fewer surgical discectomies were performed (6 vs 13, $p=0.04$).

Conclusion The addition of a short course of adalimumab to the treatment regimen of patients with acute and severe sciatica resulted in a small decrease in leg pain and in significantly fewer surgical procedures.

Comments This study is now accepted for publication in A&R.

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