

# **Subcutaneous Injection of Adalimumab Trial compared with Control (SCIATiC): a randomised controlled trial of adalimumab injection compared with placebo for patients receiving physiotherapy treatment for sciatica**

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## Plain English summary

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## Plain English summary

Sciatica is a severe leg pain usually caused by inflammatory chemicals released from a ruptured intervertebral disc irritating a nerve as it leaves the spine. Biological treatments such as adalimumab (Humira®, AbbVie Ltd, Maidenhead, UK) block the effects of these chemicals and may be effective for treating sciatica.

We aimed to test whether or not adalimumab injections plus physiotherapy are more effective, and better value for money, than saline injections plus physiotherapy for patients with sciatica.

Participants were adults with sciatica for 1–6 months and with moderate or high disability. They were referred from primary care and musculoskeletal services to outpatient physiotherapy clinics. They received, at random, either two doses of adalimumab or saline injections. Both groups were referred for a course of physiotherapy treatment.

Outcomes were measured at the start, and after 6 weeks' and 6 months' follow-up. The main outcome was back pain-related disability. Other outcomes measured leg pain disability, bothersomeness, general health, anxiety, depression, resource use, predictors of disability and adverse effects.

We planned to recruit 332 participants, with the first 50 taking part in a pilot study. Unfortunately, only eight participants were recruited from two out of six sites. Of the other four sites, one dropped out, one failed to complete contract negotiations and two did not sign their contracts until just before trial closure. In the two sites that did recruit participants, large numbers of invitations were sent, but uptake was poor. Two sites planned to recruit participants during general practitioner consultations but opened too late to recruit.

The research question is still an important one to answer. A number of factors contributed to poor recruitment: contracts, inefficient identification of participants, delays in site set-up and lack of investigator engagement. Because of this, we were not able to complete the internal pilot or test all of the different methods for primary care recruitment that we had planned.



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