Duloxetine for chronic sciatica (DREAM): an adaptive randomised placebo-controlled trial

ACTRN12624000919516

Status	RECRUITING
Phase	Phase 4
Sponsor	The University of Sydney
Enrollment	332 participants

Plain Language Summary

Sciatica is a shooting or burning pain that travels down one leg, caused by irritation of the nerves coming out of the lower spine. For many people it resolves within weeks, but roughly half of those who develop it still have significant pain a year later — and options for treating chronic sciatica are limited. This study is testing whether duloxetine, an antidepressant that also works on pain pathways in the nervous system, can meaningfully reduce leg pain in people with chronic sciatica.

The DREAM trial is a large, well-designed randomised placebo-controlled study that will definitively answer whether duloxetine works for this condition. Participants will be randomly assigned to receive either duloxetine or a placebo tablet, and will be followed over time to track their pain levels and quality of life.

Adults aged 18 or older who have had radiating leg pain for at least three months, with signs of nerve root involvement confirmed by clinical examination or imaging, and moderate or severe leg pain at the time of enrolment may be eligible. You must not currently be taking any antidepressants and must be able to communicate adequately in English. People who have had recent spinal surgery, a planned spinal procedure within 12 weeks, serious kidney or liver disease, or contraindications to duloxetine are not eligible. The trial is led by the University of Sydney.

Key Eligibility Criteria

Inclusion (5)

- Adults (18 years old and above) with radiating pain into one leg in a dermatomal distribution
- Leg pain duration of at least three months
- Evidence of nerve root involvement, defined by the presence of at least ONE of the following clinical signs in the corresponding distribution: myotomal weakness and/or diminished reflex and/or sensory deficit and/or imaging evidence of nerve root impingement that is consistent with the clinical presentation.
- Leg pain that is at least moderate in intensity at the time of enrolment by a study doctor (as measured by a modified version of item 21 in the 36-Item Short Form Survey Instrument).
- An adequate understanding of English or the availability of interpretation services for the participant to complete the trial.

Exclusion (10)

- Known or suspected specific pathologies in the spine (e.g. fracture, cauda equina syndrome).
- Known or suspected malignancy.
- Having had spinal surgery or other interventional procedure (e.g. epidural injection) in the preceding 6 months.
- Scheduled to have a spinal procedure (e.g. spinal surgery, epidural injection) within 12 weeks at the time of enrolment.
- Currently using any antidepressant for any condition.

... and 5 more (see full listing online)

Locations (1 total)

ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000919516