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Comparing two types of epidural for sciatica pain

Submission date
03/08/2022

Recruitment status
No longer recruiting

Registration date
05/08/2022

Overall study status
Completed

Last Edited
17/08/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Low back pain is a burden to both patients and the NHS and is associated with increased disability and poor sleep, with detrimental effects on patients' quality of life.

Sciatica (or lumbosacral radiculopathy), is due to compression of the nerves in the lower back, resulting in back pain and hip which radiates down the back of the thigh and the leg. It is routinely treated with steroid injection into the back (epidural).

The most common type of epidural for sciatica is called a transforaminal epidural, where the needle is inserted into a bony opening where nerves exit the spinal cord. The standard way of performing this injection, called the supraneural method, has a good overall safety profile, but there have been very rare reports of catastrophic injury resulting in paraplegia. This is thought to be due to damage to a specific artery during the epidural. An alternative method, called the infraneural approach, avoids this artery and removes the risk of injury (Figure 1).

Both the supraneural and the infraneural routes are effective in treating sciatica and both are used in Aberdeen, based on clinical presentation and the doctor's expertise and/or preference.

We plan to use a type of trial design called a 'non-inferiority trial' to show that the infraneural approach is not worse than the supraneural approach in terms of effects on pain, disability and sleep. This will inform us whether a recommendation to routinely use the infraneural technique is appropriate, since this would remove the potential for catastrophic outcome.

Who can participate?
Eighty-two patients with moderate/severe sciatic pain who are scheduled for epidural at the pain clinic at Aberdeen Royal Infirmary

What does the study involve?
We will randomly assign them (like tossing a coin) to receive their epidural using one of the two techniques. Only the doctor giving the epidural will know which technique has been used; the other researchers and participants will not know until the end of the study.
Participants will wear an activity watch for a week before their treatment and will input daily

pain scores. At the beginning and end of the week participants will be asked to complete questionnaires about their pain, functional disability and sleep. After the epidural, they will wear the activity watch for a week immediately after the treatment and complete the questionnaires again, repeated after 1, 2 and 3 months. At the end of 4, 6, 9 and 12 months they will again complete the questionnaires; we will be following them up for a total of a year.
We will determine the difference between the effect of the two epidural techniques. After the study, we will also ask participants to provide feedback to ensure their views contribute to future study design. Participants' medical treatment will not be affected or delayed by participating.
What are the possible benefits and risks of participating?

Where is the study run from?
University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?
June 2022 to September 2025

Who is funding the study?
British Journal of Anaesthesia (UK)

Who is the main contact?
Prof Helen Galley, h.f.galley@abdn.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2022-000679-38

Integrated Research Application System (IRAS)

1005202

Protocol serial number
3-013-22

Study information

Scientific Title
Supraneural versus Infraneural Approach to transforaMinal Epidural StEroid injection for unilateral lumbosacral radicular pain (SIAMESE): A randomised non-inferiority trial.

Acronym
SIAMESE

Study objectives
This is a randomised non-inferiority trial of two approaches for transforaminal epidural steroid injection. We hypothesize that the infraneural approach is not inferior to the supraneural approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Interventional randomized single blind non-inferiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lumbosacral radicular pain (sciatica)

Interventions
Participants will be in the trial for 12 months in total, with 7 trial visits. Once consent has been obtained the researcher will provide participants with questionnaires and a programmed Actiwatch. Participants will wear their Actiwatches and input daily pain scores for one week prior to epidural, one week after, then again for a week after 1 and 3 months. Subjects will complete the pain, sleep and physical functioning questionnaires at each visit. They will also complete a screening questionnaire for depression at visits 1 and again at visit 4.

Participants will receive transforaminal epidural steroid injection as per routine clinical care and will be randomized to one of two types of epidural approach.
Arm A: Supraneural transforaminal epidural steroid injection
In this approach, the disc-nerve interface at lateral recess is best achieved from the level below. So, the foraminal entry/needle placement will be one level below the radiologically confirmed

level (the L5/S1 foramen will be entered for L4/5 disc prolapse). Digital subtraction angiography will be used at the discretion of the clinician. Images (X-rays) from at least three views should be saved so that needle placement can be evaluated.
Arm B: Infraneural transforaminal epidural steroid injection
In this approach, the disc-nerve interface at lateral recess is best achieved at the same level. So, the foraminal entry/needle placement will be the same level as the radiologically confirmed level (the L4/5 foramen will be entered for L4/5 disc prolapse). Digital subtraction angiography will be used at the discretion of the clinician. Images (X-rays) from at least three views should be saved so that needle placement can be evaluated.

Participants will be randomised to receive their epidural injection by one of the two routes of administration immediately prior to the epidural. A schedule will be pre-prepared by an external statistician not involved in the study. The sealed envelopes will be pre-prepared according to this schedule by a member of staff unrelated to the trial. The researcher will select the correct envelope for the participant ID number and personally hand this to the treating clinician immediately prior to the theatre session.

Intervention Type
Other

Primary outcome(s)
Weighted-average pain intensity numerical rating scores at 3 months after epidural injection.

Key secondary outcome(s))
1. Pain intensity scores at 1 week and 1, 3, 6, 9 and 12 months using numerical rating scale.
2. Objective sleep parameters and activity at 1 and 3 months measured using an Activity watch.
3. Subjective sleep parameters at 1 week and 1, 3, 6, 9 and 12 months using the Pain and Sleep Questionnaire three item index sleep scale.
4. Physical functioning scores at 1 week and 1, 3, 6, 9 and 12 months using the Oswestry Disability Index.
5. Emotional functioning scores at 3 months using the Patient Health Questionnaire
6. Requirement for additional treatments during the study (12 months)
7. Adverse events related to the epidural at 2 weeks

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Sciatica secondary to prolapsed intervertebral disc
3. At least 3 months of symptoms
4. Leg pain of 5 or more on 0-10 NRS, not responsive to at least one form of conservative treatment
5. Diagnosis confirmed by magnetic resonance imaging (MRI) showing paracentral disc bulge filling the lateral recess

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age under 18 years
2. Sciatica due to fixed lesions such as facet or ligamentous hypertrophy, far lateral disc bulge, spinal stenosis, or spondylolisthesis
3. History of epidural steroid injection in the last 12 months
4. History of spinal surgery at any lumbar levels
5. Serious neurological deficit
6. Anatomical abnormalities posing technical challenges or contraindication to one of the injection routes and precluding randomisation
7. Pregnancy*
8. Active metastatic disease
9. Cancer or infection as a cause of back pain
10. Inability to provide written informed consent
11. Adults with incapacity
12. Vulnerable adults, as defined by Adult Support and Protection (Scotland) act (2007)

Date of first enrolment
01/10/2022

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
NHS Grampian

ROR
https://ror.org/00ma0mg56

Organisation
University of Aberdeen

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Research organisation

Funder Name
British Journal of Anaesthesia

Alternative Name(s)
British Journal of Anaesthesia Ltd, BJA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be made available on reasonable request
h.f.galley@abdn.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/02/2023	17/08/2023	Yes	No