ISRCTN04820368 https://doi.org/10.1186/ISRCTN04820368

NErve Rootblock VErsus Surgery: NERVES

Submission date
03/06/2014

Recruitment status
No longer recruiting

Registration date
05/06/2014

Overall study status
Completed

Last Edited
11/05/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study of about 200 patients suffering from sciatica resulting from a prolapsed (slipped) disc. The aim is to establish if local anaesthetic and steroid injection (TFESI) administered accurately to the source of radicular leg pain can provide a faster, cheaper and more effective treatment for patients with persistent sciatica than an invasive surgical procedure (microdiscectomy). The studys findings should help advise clinicians on which treatment type may bring the most benefit to patients.

Who can participate?
Patients aged 16 or over with recently diagnosed sciatica secondary to a prolapsed disc with symptoms of between 6 weeks and 12 months in duration.

What does the study involve?
The trial will be run in out-patient NHS neurosurgical, pain and orthopaedic clinics. Patients who would like to take part will be allocated to either the epidural steroid injection or microdiscectomy by a process called randomisation with an aim for a 50/50 split of each treatment. The treatment will take place between 4-6 weeks after randomisation. 3 months after treatment the patient will be asked to complete questionnaires to assess how successful the treatment has been. These questionnaires will be repeated at 6, 9 and 12 months to measure the ongoing results of the treatment options.

What are the possible benefits and risks of participating?
Both of the treatment options offered as part of this trial are currently used by the NHS as treatments for sciatica secondary to a prolapsed disc and are considered effective therapies. There should be benefits to all patients suffering acute radicular leg pain as this should help guide treatment options for these patients in the future. The side effects are those commonly associated with spinal surgery or injection; these are well documented.

Where is the study run from?
The lead centre for NERVES is The Walton Centre for Neurology and Neurosurgery NHS Foundation Trust. It is anticipated that several other specialist centres in Manchester, Cambridge, Glasgow, Preston, Leeds and Middlesborough will also be involved.

When is study starting and how long is it expected to run for?
January 2015 to July 2019

Who is funding the study?
National Institute of Health Research Health Technology Assessment (NIHR HTA)

Who is the main contact?
Mr Martin Wilby
nerves@liverpool.ac.uk

Study website
http://www.nervestrial.org.uk/

Contact information

Type(s)
Scientific

Contact name
Mr Martin Wilby

Contact details
The Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7LJ
-
nerves@liverpool.ac.uk

Type(s)
Scientific

Contact name
Ms Hannah Short

Contact details
Clinical Trials Research Centre
Institute of Child Health
Alder Hey Children's NHS Foundation Trust
Eaton Road
Liverpool
United Arab Emirates
L12 2AP
+44 151 794 9768
nerves.trial@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number
2014-002751-25

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/201/10

Study information

Scientific Title
Multi-centre randomised control trial comparing the clinical and cost effectiveness of trans-foraminal epidural steroid injection to surgical microdiscectomy for the treatment of chronic radicular pain secondary to prolapsed intervertebral disc herniation: Nerve rootblock versus surgery (NERVES)

Acronym
NERVES

Study objectives
This study is designed to provide an evidence base to potentially inform future treatment of sciatica secondary to prolapsed disc. Transforaminal epidural steroid injection is recognised as a treatment alternative to surgical microdiscectomy, but it is not known how effective and cost effective this treatment is in comparison. This trial will compare the epidural steroid injection and microdiscectomy, and examine the impact of the different treatment modalities on several outcomes such as Oswestry Disability Questionnaire scores, return to work, and other health economic analyses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West – Liverpool Central, 08/10/2014, ref: 14/NW/1219

Study design
Open labelled 2-arm randomised controlled trial with an inbuilt pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Acute sciatica secondary to prolapsed intervertebral disc

Interventions
The technologies to be compared are:
1. Fluoroscopically guided trans-foraminal epidural steroid injection (TFESI) of a standard combination of local anaesthetic and steroid drug and
2. Standard surgical lumbar microdiscectomy

Intervention Type
Procedure/Surgery

Primary outcome measure
Pilot Study (recruitment from 2 sites for 6 months):
Predicted full trial recruitment period <18 months and consent rate >40%

Full study:
Oswestry Disability Questionnaire (ODQ; a condition specific outcome measure with over 30 years of scientific validation) at 3 months post-intervention

Secondary outcome measures
1. ODQ at 6 months post intervention
2. ODQ at 9 months post intervention
3. ODQ at 12 months post intervention
4. Visual analogue pain scores for leg and back pain
5. Likert Scale
6. Modified Roland-Morris outcome scale for sciatica
7. Core Outcome Measures Index (COMI)
8. Work status (return to work)
9. QOL
10. Health economic outcomes expressed as the incremental cost per quality-adjusted life-year (QALY)

Overall study start date
17/07/2014

Completion date
09/07/2019

Eligibility

Key inclusion criteria
As of 19/05/2016:
1. Diagnosed lower extremity radiculopathy (sciatica)
2. Sciatica secondary to prolapsed intervertebral disc (PID) (proven on MRI)
3. Duration of symptoms between 6 weeks and 12 months

4. Leg pain non-responsive to conservative, non-invasive management
5. Age 16 – 65 years
6. Patient has attempted at least one form of conservative (non-operative) treatment* but this has not provided adequate relief of patient's pain/symptoms
7. Patient willing and able to give consent

*including but not limited to; medication, physiotherapy, modification of daily activities

Previous inclusion criteria:
1. Newly diagnosed disabling sciatica secondary to prolapsed intervertebral disc (proven on MRI)
2. Duration of symptoms between 6 weeks and 6 months
3. Failed conservative, non-invasive management
4. Age over 16 years
5. Diagnosed with lower extremity radiculopathy (sciatica) secondary to a lumbar disc herniation
6. Medication has not been helpful in treating the patient's pain/symptoms
7. Modification of daily activities has not been helpful in treating the patient's pain/symptoms
8. Physiotherapy has not been helpful in treating the patient's pain/symptoms
9. Patient willing to give consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
148 (updated 06/04/2020, previously 200)

Total final enrolment
163

Key exclusion criteria
As of 19/05/2016:
1. Serious neurological deficit (e.g. foot-drop/possible cauda-equina compression)
2. Previous spinal surgery at the same intervertebral disc (level)
3. Sciatica presentation for longer than 12 months
4. Age < 16
5. Age > 65
6. Patient has not attempted any form of conservative treatment
7. Any patient who has a contraindication for surgery and/or injection
8. Patient known to be pregnant

Previous exclusion criteria:
1. Neurological deficit (foot-drop/possible cauda-equina compression)
2. Previous surgery at that level
3. Age: < 16
4. Any patient who has not attempted conservative non-operative treatment for a minimum of 6 weeks

5. Any patient who has a contraindication for surgery
6. Any patient who is pregnant

Date of first enrolment
17/07/2014

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Walton Centre NHS Foundation Trust
Liverpool
United Kingdom
L9 7LJ

Sponsor information

Organisation
The Walton Centre NHS Foundation Trust (UK)

Sponsor details
c/o Gillian Hamblin
The Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
England
United Kingdom
L9 7LJ
+44(0)151 556 3389
Gillian.Hamblin@thewaltoncentre.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.thewaltoncentre.nhs.uk

ROR
https://ror.org/05cvxat96

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/11/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/09/2018		Yes	No
Results article		01/04/2021	14/04/2021	Yes	No
Results article		18/03/2021	11/05/2021	Yes	No
HRA research summary			28/06/2023	No	No