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Investigating the role of advanced MR imaging in assessing patients with trapped nerves in the neck

Submission date
04/08/2020

Recruitment status
No longer recruiting

Registration date
19/10/2020

Overall study status
Completed

Last Edited
17/03/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Currently standard MRI scans for trapped nerves in the neck are performed using sequential horizontal and vertical cuts through the spine separated by 2 or 3 mm. However, the nerves travel in a canal that is neither in the horizontal or vertical plane and the nerve itself is 2 to 3 mm in diameter. Consequently, nerve root compression can be rather poorly demonstrated on standard MRI sequences. Furthermore, the currently published scoring systems are not well-validated and therefore rarely used in clinical practice. In this study, the researchers will be using standard MRI techniques but at a different angle to image the nerves in the neck at high resolution as they leave the spine. The scans will be angled so that they cut exactly along and across the nerve canal. The aim is to see how this imaging matches the symptoms and whether different locations of compression better respond to one of the two main operations that can be performed.

Who can participate?
Patients who are awaiting surgery to treat cervical brachialgia (pain produced by a trapped nerve in the neck)

What does the study involve?
Participants will have some information recorded and have an additional MRI scan performed before their surgery. Their symptoms will be assessed 1 day and 6 weeks after the surgery. The researchers will measure the width of the nerve canal on standard images and on the images angled along and across the nerve to see which technique is best at predicting the symptoms of nerve root compression and the response to surgical decompression.

What are the possible benefits and risks of participating?
It is expected that the new technique will permit better selection of patients for surgery and inform decisions on whether to perform surgery from the front or from the back of the neck. There are no risks to the participants expected through the use of a clinical MRI machine. All

images will be reviewed by a consultant neuroradiologist to exclude unexpected findings. Should an unexpected finding be discovered the participant's GP will be informed and the appropriate clinical referral will be made

Where is the study run from?
Leeds General Infirmary (UK)

When is the study starting and how long is it expected to run for?
September 2018 to August 2023

Who is funding the study?
1. Leeds Neurosurgical Research Fund (UK)
2. Royal College of Surgeons of England (UK)

Who is the main contact?
Dr James Meacock
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Contact information

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Scientific

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
285222

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 285222

Study information

Scientific Title
Assessing cervical foraminal stenosis: volumetric MRI study in patients with cervical brachialgia

Study objectives
There is no difference in the ability of standard imaging and modified plane imaging to predict surgical outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/06/2020, Leeds Teaching Hospitals NHS Trust (Great George St, Leeds, LS1 3EX, UK; +44 (0)113 2060483; anne.gowing@nhs.net, ltht.researchoffice@nhs.net), no ref provided

Study design
Non-randomized single-institution study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cervical foraminal stenosis leading in patients with radiculopathy

Interventions
Pre-operative patients will be recruited from surgical waiting lists with symptomatic cervical brachialgia for at least six weeks.

An additional three-dimensional volumetric MRI scan of the cervical spine will be performed. The data from this will be used to build “standard” T2 axial views with a 2 mm slice thickness. The data will also be used to build modified plane images that align with and are at cross section to the nerve root.
Clinical data including the presence of arm pain, neck pain, arm sensory or motor changes will be assessed. The neck disability score will be used as a functional score. Baseline assessments will be made on the day of surgery, one day and six weeks after the operation.

The anatomy of the cervical nerve root canal will be analysed to measure the degree of maximal nerve root compression and the length and position of this compression. We will compare the ability of standard and modified plane images to predict clinical symptoms and surgical outcome. Inter and intra rater consistency will also be measured for each type of scan.

Automated mathematical modelling measurements of the root canals will also be made, and the consistency of these measurements calculated.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Standard magnetic resonance imaging (MRI), modified plane MRI

Primary outcome(s)
Self-rated disability assessed using Neck Disability Index (NDI) at 6 weeks post-surgery

Key secondary outcome(s))
1. Self-rated disability assessed Neck Disability Index (NDI) at 1 day post-surgery
2. Pain intensity assessed using Numerical Rating Scales for neck and upper limb pain 1 day and 6 weeks post-surgery.
3. Neuropathic pain assessed using PainDETECT at day 0 and at 1 day and 6 weeks post-surgery
4. Extent and severity of spinal cord and upper limb functional impairment assessed using a restricted version of the ASIA score at the pre-operative assessment and at 1 day and 6 weeks post-surgery
5. Complications occurring during the initial trial operative procedure and postoperative complications recorded up to 6 weeks post-surgery

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Diagnosis of brachialgia
3. Able to provide fully informed written consent
4. Able to lie flat for 1 hour in an MRI scanner
5. Awaiting either an anterior cervical discectomy or a posterior cervical foraminotomy for

brachialgia
6. Females of childbearing age must be using effective contraception
7. Sufficient understanding of English to participate in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
11

Key exclusion criteria
1. Cervical myelopathy
2. Radiological evidence of cord compression
3. History of cervical trauma
4. Evidence of suspected or histologically proven tumour
5. Previous cervical spine surgery
6. Non-MRI compatible implantable device e.g. pacemaker
7. Unable to have MRI scan due to claustrophobia
8. Female participants must not be pregnant and if of childbearing age must be using adequate contraception

Date of first enrolment
01/04/2021

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Teaching Hospitals NHS Trust
Leeds General Infirmary

Great George Street
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Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Research organisation

Funder Name
Leeds Neurosurgical Research Fund

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Simon Thomson (S.Thomson@leeds.ac.uk) on study publication for 7 years for researchers wishing to confirm the findings or undertake metanalysis by secure data transfer, consent from participants was obtained, data will be anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet version V5	11/11/2025	11/11/2025	No	Yes
Protocol file		19/10/2020	19/10/2020	No	No