

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/03/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

285222

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Standard magnetic resonance imaging (MRI), modified plane MRI

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/09/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

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

England

United Kingdom

Study participating centre

Leeds Teaching Hospitals NHS Trust

Leeds General Infirmary

Great George Street

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

Leeds Teaching Hospitals NHS Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.leedsth.nhs.uk/home/>

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

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The study will be registered with an authorised registry, according to the International Committee of Medical Journal Editors (ICMJE) Guidelines, prior to the start of recruitment.

The success of the study depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the study, through authorship and contribution. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

1. Conception and design, or acquisition of data, or analysis and interpretation of data
2. Drafting the article or revising it critically for important intellectual content
3. And final approval of the version to be published,
4. And that all these conditions must be met (<http://www.icmje.org>)

In light of this, the Chief Investigator and other investigators will be named as authors in any publication.

To maintain the scientific integrity of the study, data will not be released prior to the first publication of the analysis of the primary endpoint, either for study publication or oral

presentation purposes. It is planned that publications will be in a high-impact peer-reviewed journal.

Intention to publish date

01/12/2025

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?
Protocol file	version V5	19/10/2020	19/10/2020	No	No