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Comparing the clinical and cost effectiveness of two types of neck surgery, posterior cervical foraminotomy (PCF) and anterior cervical discectomy (ACD), for the treatment of cervical brachialgia

Submission date
20/11/2018

Recruitment status
No longer recruiting

Registration date
23/11/2018

Overall study status
Completed

Last Edited
19/08/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cervical brachialgia is a type of pain that tracks from the neck down the arms, and is caused by nerve compression in the neck. There are two types of operation used to treat cervical brachialgia - posterior cervical foraminotomy (PCF), where the operation is done through the back of the neck, and anterior cervical discectomy (ACD), which involves operating through the front of the neck.
This trial aims to determine the clinical effectiveness and cost effectiveness of PCF and ACD for the treatment of cervical brachialgia.

Who can participate?
Adults with a diagnosis of unilateral cervical brachialgia as confirmed by MRI or CT myelogram, who have had symptoms for at least 6 weeks

What does the study involve?
Potential participants will be identified in neurological centres in the UK following referral from their GP. They will be given a patient information sheet and informed consent will be taken if they would like to take part. Participants will then have standard assessments performed, as well as an ASIA assessment. Participants will complete questionnaires, and randomised to receive either PCF or ACD surgery on the day of their operation.
The day after, and 6 weeks after the operation, standard assessments and an ASIA assessment will be performed on participants. On day 1, and weeks 6, 12, 26, 39 and 52 after the operation, participants will complete questionnaires.
25% of participants will also have a voice recording taken to assess if their voice is affected by the operation, before surgery and 6 weeks after surgery.

What are the possible benefits and risks of participating?
Treatment in the trial is the same as standard of care, and so the risks and benefits are the same as if the patient did not take part. The possible benefit is that the surgery may alleviate the participants' symptoms. The possible risk is complications of surgery.

Where is the study run from?
The study is run from the Clinical Trials Research Unit (CTRU) at the University of Leeds (UK). It will take place at Leeds General Infirmary and other neurosurgical centres across the UK

When is the study starting and how long is it expected to run for?
November 2018 to June 2022

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Rachel Kelly, forvad@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 39563

Study information

Scientific Title
FORVAD: clinical and cost-effectiveness of posterior cervical FORaminotomy Versus Anterior cervical Discectomy in the treatment of cervical brachialgia: a multicentre, phase III, randomised controlled trial

Study objectives
The aim of the study is to determine the clinical and cost effectiveness of posterior cervical foraminotomy (PCF) compared to anterior cervical discectomy (ACD) in the treatment of patients with cervical brachialgia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester Central Research Ethics Committee, 19/11/2018, 18/NW/0682

Study design
Interventional randomized controlled parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Cervical brachialgia

Interventions
Participants will be randomly allocated to one of two groups. Each group will receive a different operation - one group will receive posterior cervical foraminotomy (PCF), which involves operating through the back of the neck, and the other group will receive anterior cervical discectomy (ACD), which involves operating through the front of the neck. Both operations are standard treatments for cervical brachialgia. Participants will be randomised to either the PCF or ACD group on the day of their surgery.
At day 1 post surgery, participants will have routine assessments performed, as well as an ASIA (American Spinal Injury Association) assessment. Participants will also complete a questionnaire pack. Participants will then attend the clinic 6 weeks post surgery for routine clinical assessment as they would as part of standard care, and have another ASIA assessment performed. Participants will then complete a questionnaire pack, and do a voice recording if applicable. On

weeks 12, 26, 39 and 52 a questionnaire pack will be sent to participants by post for completion and return by post, participants will be sent email or text reminders if they consented to this on the consent form.
25% of participants will be selected at registration to provide a voice recording. This will be completed before the operation and 6 weeks after the operation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Neck pain, assessed using the Neck Disability Index (NDI) at the baseline and 52 weeks post-surgery

Secondary outcome measures
To compare PCF and ACD in terms of:
1. Neck and upper limb pain including the shoulder, arm and hand assessed using Numerical Rating Scales, and neuropathic pain (including dysesthetic pain) assessed using the PainDETECT tool over 52 weeks post-surgery
2. Dysphagia (difficulty swallowing) and globus (sensation of a lump in the throat) over 52 weeks post-surgery as assessed by the participant-completed Eating Assessment Tool (EAT-10) and the Glasgow and Edinburgh Throat Score (GETS) questionnaires
3. Hoarse voice over 52 weeks post-surgery, assessed by the participant completed Voice Handicap Index-10 (VHI-10) and at 6 weeks for a sub-set of participants that have a central Grade, Roughness, Breathiness, Asthenia and Strain (GRBAS scale) assessment of their recorded voice
4. Extent and severity of a patient's spinal cord function, including upper limb nerve root function, using the American Spinal Injury Association (ASIA) score at 1 day and 6 weeks post-surgery
5. Incidence of revision surgery, collected on a case report form (CRF) over 52 weeks post-surgery
6. Incidence of surgical complications, collected on a CRF up to 6 weeks post-surgery
7. Cost-effectiveness, assessed by a health economist over 52 weeks post-surgery

Overall study start date
01/01/2018

Completion date
19/03/2021

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Diagnosis of unilateral cervical brachialgia as confirmed by MRI or CT myelogram taken within the last 12 months
3. Symptoms of cervical brachialgia present for at least 6 weeks
4. Single level nerve entrapment
5. Postero-lateral disc and/or foraminal narrowing
6. Failed conservative management (including but not limited to medication, physiotherapy, modification of daily activities)
7. Able and willing to comply with the terms of the protocol, including quality of life

questionnaires
8. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 252; UK Sample Size: 252

Total final enrolment
23

Key exclusion criteria
1. Cervical disc causing cord compression
2. Cervical myelopathy
3. Bilateral cervical brachialgia
4. Previous cervical spine surgery
5. Professionals where a hoarse voice would be exceptionally significant (e.g. singers or speakers)
6. Skin disease at surgical sites (e.g. eczema)
7. Pregnancy
8. Cervical deformity
9. Not suitable for anterior cervical discectomy (ACD)
10. Not suitable for posterior cervical foraminotomy (PCF)

Date of first enrolment
10/01/2019

Date of final enrolment
10/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds General Infirmary
Great George Street

Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
St. James's University Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/31/53

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
14/06/2022

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results	version 1.0	15/11/2022	23/11/2022	No	Yes
HRA research summary			28/06/2023	No	No
Results article		01/10/2023	06/11/2023	Yes	No
Other publications	qualitative study of experiences of healthcare professionals	17/08/2024	19/08/2024	Yes	No