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Does laminectomy alone or laminectomy with fusion lead to better recovery in patients undergoing surgery for degenerative cervical myelopathy from the back?

Submission date
09/02/2022

Recruitment status
Recruiting

Registration date
11/02/2022

Overall study status
Ongoing

Last Edited
03/03/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Degenerative cervical myelopathy [DCM] is a common condition caused when arthritic changes in the neck compress the spinal cord. It affects up to 2% of adults and causes numb and clumsy hands, imbalance, and bladder problems. Often it continues to worsen with time and left untreated lead to severe disability and paralysis. The only current treatment is surgery, and a number of different operations are used. The aim of surgery is to create space for the spinal cord. Surgery is able to stop further deterioration and lead to some improvements.
For people who need DCM surgery from the back of their neck, the pressure on the spinal cord is relieved by removing part of the bone that surrounds the spinal cord called the laminae. This procedure on its own is called a laminectomy. In some cases, metal implants are placed in addition to the laminectomy in order to stiffen the spine. This is called laminectomy and fusion. Both procedures have potential advantages and disadvantages. The aim of this study is to find out whether laminectomy and fusion improves outcomes following surgery for DCM compared to laminectomy alone.

Who can participate?
Patients aged 18 years and over who are scheduled to undergo posterior surgery for DCM with multilevel compression

What does the study involve?
Participants are randomly allocated to treatment with either laminectomy alone or laminectomy and fusion.

What are the possible benefits and risks of participating?
Laminectomy alone is a more straightforward and shorter surgery that does not affect the range of movement in the neck. However, without fusion a change in the alignment of the spine called deformity may develop. Some surgeons believe deformity may affect long-term recovery and may cause greater neck pain for some people. Laminectomy and fusion aims to prevent this

deformity but in doing so will greatly reduce the range of movement in the neck (particularly looking over the left or right shoulder). Some people find this a problem for everyday life, such as driving. Furthermore, the insertion of metalwork slightly increases the risks of the surgery, whilst greatly increasing the cost.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
April 2020 to November 2028

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

Who is the main contact?
Mr Stefan Yordanov, s.yordanov@nhs.net

Study website
https://polyfix-dcm.com/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297923

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 50908, IRAS 297923

Study information

Scientific Title
POsterior Laminectomy and FIXation for Degenerative Cervical Myelopathy [POLYFIX-DCM]

Acronym
POLYFIX DCM

Study objectives
Laminectomy and fusion improves outcomes following surgery for multi-level degenerative cervical myelopathy (DCM) when compared to laminectomy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2021, HRA and Health and Care Research Wales (HCRW, Castlebridge 4, 15 - 19 Cowbridge Rd E, Cardiff, CF11 9AB, UK; +44 (0)29 2023 0457; hcrw.approvals@wales.nhs.uk), REC ref: 21/YH/0253

Study design
Randomized; Interventional; Design type: Treatment, Surgery

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
Degenerative cervical myelopathy

Interventions
POLYFIX DCM will be a multi-centre pragmatic, randomised trial, with blinded outcome assessment, aiming to determine the comparative clinical- and cost-effectiveness of

decompression and fusion, with decompression alone for multi-level DCM treated posteriorly. Due to the nature of the trial, the local clinical teams, patients and carers cannot be blinded to allocation. However, by employing centralised telephone follow-up, a blinded assessment of the primary outcome can be performed. The trial will be preceded by an internal pilot in order to confirm recruitment, randomisation, treatment, and follow-up assessments.

POLYFIX DCM will address the following hypothesis: 'Laminectomy and fusion improves outcomes following surgery for multi-level degenerative cervical myelopathy when compared to laminectomy alone.'

The primary outcome measure for this trial is the modified Japanese Orthopaedic Association Score (mJOA). The mJOA was therefore selected as the single primary end-point, on the basis:
1. The recovery priorities for patients are pain, hand and walking function
2. The mJOA is the international standard, and most validated measure for the assessment of neuromuscular function in DCM and has been the primary endpoint for most leading trials. It primarily evaluates motor dysfunction in the upper and lower extremities but also altered sensation (including pain) to the hand(s) and sphincter dysfunction
3. Pain is a complex experience, and a single pain outcome tool has not been specifically validated for use in DCM
4. The NIHR HTA (funder) favoured a single primary endpoint (vs co-primary endpoint)
5. Although traditionally a clinician-administered score, a version has now been developed for use remotely, potentially more conducive to current NHS practice due to the COVID-19 pandemic

The researchers plan to include 394 participants in this trial from approximately 20-30 sites in the UK and 5-10 sites internationally. In anticipation of requirements to optimise recruitment processes they propose initially three patient focus groups of 3-6 people (one within the pilot phase, two within the substantive phase) conducted online using Zoom or an equivalent videoconferencing system. These workshops will focus on understanding individual experiences and are not designed to change their opinions. Participation will be voluntary.

Potentially eligible patients with DCM will be approached by a delegated member of the local trial team and given a participant information sheet to read in their own time. If they decide to participate in the trial, they will undergo a screening assessment to confirm their eligibility for the trial. Screening assessments will assess the following at an outpatient appointment: age, mJOA, planned surgical intervention, DCM characteristics (symptoms, length of DCM symptoms), MRI image findings (number of cervical spine levels for treatment) and a neurological examination. Following screening, eligible subjects will be randomised by an online randomisation system in a 1:1 ratio to treatment with either laminectomy alone or laminectomy and fusion. They will then be given a unique trial ID number. Each patient has the right to withdraw from the trial at any time.

The following baseline assessments will then take place: weight (kg), smoking status, psychiatric comorbidities, impaired gait, medical history (comorbidities), medication history, mJOA assessment, SF36v2 (quality of life) score (physical component score and mental component score), EQ5D-5L, patient health questionnaire (PHQ9), Generalised Anxiety Disorder Questionnaire (GAD7), Neck Disability Index (NDI), Brief Pain Inventory (BPI), Douleur Neuropathique 4 (DN4), Michigan Body Map (pain location), cervical x-rays (deformity, auto-fusion, movement), Myelopathy.org symptom inventory, (Updated) Charleston Comorbidity Index, healthcare resource use questionnaire.

The following intraoperative assessments will take place when the patient undergoes their surgical treatment: operation title, levels treated, American Society Anaesthesiology (ASA)

grade, operation duration, estimated blood loss, intraoperative complications, use of intraoperative navigation or intraoperative neuromonitoring (neurophysiology), nature of Inserted Metalwork, if applicable (number/brand) and use of synthetic products to support fusion. On discharge, the following will be assessed: length of stay and ward type, complications, other adverse events (e.g. requirement for blood transfusion) and change in medication.

Postoperatively, participants are to be reviewed at 6-, 12- and 24-months post-surgery for assessments. At each of these reviews, the following will be assessed: mJOA, SF36v2 (quality of life) Score, EQ5D-5L, Neck Disability Index (NDI), Brief Pain Inventory (BPI), Douleur Neuropathique 4(DN4), Michigan Body Map (Pain Location), complications (including surgical site infection, wound breakdown, instrument failure), adverse events, cervical x-rays (deformity, fusion, movement), Myelopathy.org symptom inventory, change in medication and healthcare resource use questionnaire.

Outcomes are largely centralised, and either conducted by the patient, or an assessor blinded to their trial arm. The only pre-defined requirement for local sites is to arrange the cervical spine x-rays.

Additionally, participants will be informed of an option to measure CarerQOL at baseline. As a chronic disease with a significant disability, patients are often dependent to some degree on those around them, which in turn affect their carers' quality of life. Contact details will be provided should the participant, or their informal carer(s) have follow up questions for the investigator team. Informal carers consenting to participate will be sent a CarerQOL to complete at baseline, discharge from hospital, 6, 12 and 24 months after surgery.

Trial participation will end 24 months post-surgery for each participant (unless consent has been given, and funding secured, for extended follow up). Following trial completion, patients will return to routine care as per their local centre protocols.

Intervention Type
Procedure/Surgery

Primary outcome measure
Neurological outcome measured using the Modified Japanese Orthopaedic Association score (mJOA) at 24 months

Secondary outcome measures
1. Pain measured using the VAS pain at 6, 12 and 24 months
2. Quality of life measured using the SF36v2 Score (Physical Component Score, Mental Component Score and Bodily Pain) at 6, 12 and 24 months
3. Quality of life measured using the EQ5D-5L at 6, 12 and 24 months
4. Pain/neck disability measured using the Neck Disability Index (NDI) at 6, 12 and 24 months
5. Pain/neck disability measured using the Brief Pain Inventory (BPI) at 6, 12 and 24 months
6. Pain measured using the Douleur Neuropathique 4 (DN4) at 6, 12 and 24 months
7. Pain measured using the Michigan Body Map (Pain Location) at 6, 12 and 24 months
8. Procedural complications, including intraoperative blood loss, dural tear, surgical site infection, wound breakdown and instrument failure, measured using case notes review at the time of surgery/post-operative period
9. Adverse events measured using patient interview, clinic and telephone visits at 6, 12 and 24 months
10. Length of hospital stay, measured using hospital electronic patient records (EPR) at discharge

11. Length of operation, measured using hospital EPR post-operatively
12. Discharge destination, measured using hospital EPR at time of discharge.
13. Alignment (C2–7 lordosis, C2–7 sagittal vertical axis and T1 slope), fusion and movement assessed using cervical, dynamic x-rays at 6, 12 and 24 months
14. Quality of life measured using the Myelopathy.org symptom inventory at 6, 12 and 24 months

Overall study start date
10/04/2020

Completion date
01/11/2028

Eligibility

Key inclusion criteria
1. Have given written informed consent to participate
2. Be aged 18 years and over
3. Have a diagnosis of DCM, based on established criteria
4. Be scheduled for posterior surgery, involving two or more consecutive laminae
5. Be able to read and understand English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 394; UK Sample Size: 394

Key exclusion criteria
1. Mild and non-progressive DCM (defined as stable mJOA score >16 at two consecutive time points)
2. Presentation in the context of acute trauma (e.g. central cord syndrome or spinal cord injury)

Date of first enrolment
01/03/2022

Date of final enrolment
01/05/2026

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

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

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
NHS Ipswich and East Suffolk CCG
Endeavour House
Russell Road
Ipswich
United Kingdom
IP1 2BX

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
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BN2 5BE

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre

Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
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CF14 4HH

Study participating centre
NHS Greater Preston CCG
Chorley House
Lancashire Enterprise Business Park
Centurion Way
Leyland
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PR26 6TT

Study participating centre
King's College Hospital NHS Foundation Trust
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SE5 9RS

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University College London Hospitals NHS Foundation Trust
250 Euston Road
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NW1 2PG

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
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E1 2ES

Study participating centre
St George's University Hospitals NHS Foundation Trust
St George's Hospital

Blackshaw Road
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SW17 0QT

Study participating centre
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United Kingdom
NG7 2UH

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
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United Kingdom
HA7 4LP

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
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LS9 7TF

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Cambridge Biomedical Campus
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research@addenbrookes.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131243

Results and Publications

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

Intention to publish date
01/11/2028

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?
HRA research summary			28/06/2023	No	No