

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

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<b>Registration date</b> 11/02/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/03/2025	<b>Condition category</b> 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

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

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

297923

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

## 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

### Study type(s)

Treatment

### 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(s)**

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

### **Key secondary outcome(s)**

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

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

Scotland

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

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United Kingdom  
IP1 2BX

**Study participating centre**

**University Hospitals of Derby and Burton NHS Foundation Trust**  
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Uttoxeter Road  
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DE22 3NE

**Study participating centre**

**Brighton and Sussex University Hospitals NHS Trust**  
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**Study participating centre**

**NHS Lothian**  
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**Study participating centre**

**Cardiff & Vale University Lhb**  
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**Study participating centre**  
**St George's University Hospitals NHS Foundation Trust**  
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**Study participating centre**  
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**Study participating centre**

**Royal National Orthopaedic Hospital NHS Trust**  
Brockley Hill  
Stanmore  
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**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**  
St. James's University Hospital  
Beckett Street  
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## **Sponsor information**

**Organisation**

Cambridge University Hospitals NHS Foundation Trust

**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**

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes