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POsterior **L**aminectom**Y** and **FIX**ation for **D**egenerative **C**ervical **M**yelopathy

POLYFIX-DCM Study
Participant Information Sheet and Informed Consent Form

https://polyfix-dcm.com

You are being invited to take part in a research study. Before deciding whether to take part, it is important that you understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Who is this information sheet for?

You may be reading this information sheet because you have been diagnosed with degenerative cervical myelopathy, commonly referred to as DCM for short. DCM is caused by wear and tear of tissues including bone, joints and ligaments in your neck leading to pressure on your spinal cord. It is common and thought to affect up to 1 in 50 adults causing problems such as clumsy hands, difficulty walking, pain and bladder problems.

What are the treatments for DCM?

For progressive, or moderate to severe DCM, the only current evidence-based treatment is surgery. Surgery can often stop symptoms from getting any worse and lead to some improvement, however full recovery is rare.

What are the surgical options?

Surgery can be undertaken to relieve the pressure on the spinal cord. The approach to the spinal cord can be through an incision in the skin on either the front or the back of the neck. So far, studies have not shown a difference in effectiveness of surgery from the front and the back, but there may be specific circumstances leading your surgeon to favour one over the other.

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 to stiffen and support the spine bones. This is called *laminectomy and fusion*.

Both procedures have potential advantages and disadvantages.

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. In addition, the insertion of metal work slightly increases the risks of the surgery.

At present both *laminectomy* and *laminectomy and fusion* are commonly performed, but experts are divided on whether one operation is better than the other.

What is the POLYFIX-DCM study?

The POLYFIX-DCM study aims to compare the *laminectomy* vs *laminectomy and fusion* operations to determine whether one of these two operations is better than the other. Finding this out has been set as a priority by a large international group of people living and working with DCM, as part of RECODE-DCM (https://aospine.aofoundation.org/research/recode-dcm)
The study will allow us to improve our treatments in the future.

POLYFIX-DCM will not study operations performed from the front of the neck.

How does this affect me?

Because we currently do not know which of the two operations is better, the operation people with DCM are offered is largely determined by the opinion of the individual surgeon. Surgeons in the UK are currently divided about 50:50 on whether to offer *laminectomy* or *laminectomy and fusion.*

In agreeing to take part in this study, you would be randomly assigned to one of the two operations, rather than leaving the decision to your individual surgeon. The randomisation element is important to the study to ensure it is fair test and that we can trust the results.

Do I have to take part?

Participating in this study is completely voluntary. If you decide to participate, you are still free to change your mind and leave the trial at any time without giving a reason. If you chose not to participate or wish to leave the trial, your future medical treatment will not be affected in any way and you will continue to receive the same standard of care.

What will I have to do if I take part?

If you agree to take part, you will be asked to sign the informed consent form at the end of this document and will be given a copy to take away with you. Your clinical care will continue as normal. The only change will be that you will be allocated to have either laminectomy or laminectomy with fusion by a process called randomisation and will therefore have a 50:50 chance of which operation you receive. Your surgeon will be able to perform the operation to which you are allocated. Your clinical care and follow up will continue as standard, however you will be asked to complete additional questionnaires assessments. We anticipate that the main assessments will be conducted by telephone.

What are the disadvantages and risks of taking part?

There are no expected negative effects to your health or wellbeing because of taking part. You will continue to receive the normal standard care for DCM. Your will be asked to complete additional questionnaires at six, twelve and twenty-four months after your operation. We will endeavour to schedules these at the same time as your routine clinical appointments if possible and the results will be available as additional information to assist your clinical team in your clinical care. You will be able to complete many of the assessments online, however paper copies via post will also be available.

As for any surgical procedure, the operations involved in this trial carry potential risks. These are broadly the same and are summarised below. As part of this trial you would undergo close observation for these.

Common More often than 1 in 100 times "A person on a street"	**Uncommon** Approximately 1 in 1000 times "A person in a village or small town"	**Rare** Approximately 1 in 10, 000 "A person in a large town"
• Dural tear • CSF leak • Epidural Haematoma • Neurological root injury (including C5 Palsy) • Worsening myelopathy • Post-operative red eye • Swallowing difficulties • Hoarse Voice • Neck Pain • Adjacent segment disease • Drowsiness, confusion or restlessness • Nausea and/or vomiting • Soft tissue infection • Urinary tract infection • Respiratory infection	• Inadequate Decompression • Spinal cord injury • Injury to the mouth or teeth from intubation or the breathing tube • Myocardial Infarction • Respiratory problems	• Blindness • Vertebral artery injury • Wrong level surgery • Anaphylaxis • Stroke • Cardiac Arrest

For those undergoing laminectomy alone, there is an unknown risk of subsequent deformity (which is one of the reasons for undertaking this study)

For those undergoing laminectomy and fusion, the insertion of metal work carries some additional, but uncommon risks: the metal work can be misplaced, it can fail (i.e. break) or fail to provide the long-term bone fusion

Additionally, if you take part in this study, you will have x-rays of your neck at a number of different time points. Some of this imaging may be extra to that which you would have had if you did not take part. These procedures use ionising radiation to form images of your body. Ionising radiation may cause cancer many years or decades after the exposure. This is very unlikely. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will add only a very small chance of this happening to you.

What are the benefits of taking part?

In participating in the study, you will undergo either *laminectomy* or *laminectomy and fusion* operations which are both currently routine standard of care for people with DCM. In addition, taking part will allow us to study whether one of the two operations is better than the other, to help others like you in the future. Taking part is therefore not primarily expected to help you or your treatment at the present time. However, the results of the additional assessments will be available for your clinical team to help inform your care.

What are the alternatives for treatment?

The alternatives for treatment are routine standard care, which would involve your individual surgeon choosing to perform either *laminectomy* or *laminectomy and fusion* based on their own individual preference.

What happens when the trial stops?

You will continue to be treated and managed as per the routine standard of NHS care. We may ask to follow your progress regularly over the 5 years following the study if further study funding is awarded. This would involve regular assessments similar to those conducted during the study, such as a yearly telephone assessment and is optional.

Expenses & Payment

We do not anticipate you will incur any expenses by participating in this study. The cost of any extra travel that is needed as part of the study (and falls outside of normal care) will be covered. If we ask you to complete a postal questionnaire, we will send a pre-stamped addressed envelope for your reply. You will not receive any payment for participating in this study.

Will my taking part in this study be kept confidential?

Once we collect your clinical data, your identifiable details will not be attached to it. Instead, your data will be given a unique study identification number (study ID). You will not be identifiable from this information.

The trial team will collect additional healthcare information such as admission to hospital, by using your NHS/CHI number to access data from NHS Digital. This involves collecting, processing, and transferring your personal data (name, gender, date of birth, postcode, and NHS/CHI number) for medical research purposes. Once the data has been linked and collected, your personal identification details will be removed for the analysis.

Equivalent national health record organisations exist in Wales (Secure Anonymised Information Linkage, Public Health Wales), Scotland (electronic Data Research and Innovation Service, Public Health Scotland) and Northern Ireland (Belfast Health and Social Care Trust). If you live in these areas, the same central healthcare records will be obtained from these sources.

You should discuss your participation in this trial with any insurance provider you have (e.g. travel insurance, protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate your cover.

Who is in charge of my personal data in this study?

Cambridge University Hospitals NHS Foundation Trust (CUH) and the University of Cambridge are the sponsors for this clinical trial in the United Kingdom. They will be using information from you and your medical records to undertake this trial and will act as the data controller for this trial. This means that they are responsible for looking after your information and using it properly. The sponsor organisations will keep identifiable information about you for a maximum of 5 years after the trial has finished ensuring your safety and allowing the trial to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the sponsor organisations need to manage their information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how the Sponsors use your information using the information below:

- For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk
- For University of Cambridge, please visit:
https://www.medschl.cam.ac.uk/research/information-governance/ or email
The Information Governance team at: researchgovernance@medschl.cam.ac.uk

[For participants recruited at CUH (where the Sponsor is also the site). Delete paragraph when localising document at other sites]

Cambridge University Hospitals will collect your name, NHS number, contact details, gender and date of birth to send you follow up questionnaires, contact you by telephone, access your health records, make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Individuals from the sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial. Cambridge University Hospitals will pass these details to the sponsors along with the information collected from and/or your medical records. The only people in the sponsor organisations who will have access to information that identifies you will be people who need to contact you in relation to this trial and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about you from this trial for a maximum of 5 years after the trial has finished.

[For participants recruited at other participating sites. Delete paragraph when localising document at CUH]

We will pass personal information about you (your name, NHS number, contact details, gender and date of birth) to the sponsor organisation to send them follow up questionnaires, contact you by telephone and access their health records. Patient identifiable information will be stored securely and the only people in the sponsor organisations who will have access to information that identifies you will be people who need to contact you in relation to this trial and to audit the data collection process.

(Add site name) will keep identifiable information about you from this study for ### years after the study has finished.

You can be reassured that your personal details and identity will be kept confidential. Your personal and medical information will be kept in a secured file and be treated in the strictest confidence. The only exception to that would be in the unlikely event that the study team discovered something that suggested you or someone else would be at risk of serious harm.

Once you have agreed to participate in this trial, you will be allocated a trial ID Number. This is a unique trial number which will be used on all your trial documentation along with your date of birth. Your date of birth is considered to be personal information. We collect this personal information on trial documentation to help ensure that the data we receive as part of your trial participation is correctly allocated to you. By cross checking these two unique references we can ensure the integrity of the data.

The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Only anonymous trial data, without any personal information will be published at the end of the trial.

Cambridge University Hospitals will also collect information about you for this trial from the national health record organisations mentioned above. This information will include your name, gender, date of birth, postcode, and NHS number and health information, which is regarded as a special category of information. We will use this information to follow any hospital admissions you have during the trial.

We will need to inform your GP of your participation in this trial so that any medical decisions made by your GP account for any treatment you are receiving as part of this trial. If you are transferred to a local hospital or rehabilitation centre, your doctors may contact the trial team to let us know where you are.

When you agree to take part in the research study, the information about your health and care may be provided to researchers running other research studies in this organisation and other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with any other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or affect your care in any way. It will not be
used to make decisions about future services available to you, such as insurance. You can find our more information about how we use your information by contacting members of the research team.

What if new information becomes available?
Sometimes during the course of a trial, new information becomes available which might affect your decision to continue participating in this trial. In this eventuality, your surgeon will contact you to discuss the new information and whether you wish to continue participating in the trial. If you still wish to continue in the trial, you will be asked to sign a new consent form.

The trial sponsor, the regulatory authority or the trial doctors may decide to stop the trial at any time. If that happens, we will tell you why the trial has been stopped and arrange for appropriate care and treatment.

What if I change my mind?
Participating in this study is completely voluntary.

If you do decide to participate you will be asked to sign an informed consent form, however you are still free to change your mind and leave the study at any time without giving a reason. However, any data already collected will continue to be used in the study.

Deciding not to take part or initially agreeing to take part but then changing your mind will not influence your current or future medical care or the success of your operation or your recovery. However, taking part will help us better understand your condition so that we improve treatments for you and others like you in the future.

What happens if something goes wrong?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be fully addressed. If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the Patient Advice and Liaison Service (PALS) at XXXXX

In the event that something does go wrong and you are harmed by taking part in the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust or the University of Cambridge, but you may have to pay to pursue this. The normal NHS complaints mechanisms will also be available to you. The researchers have obtained insurance through the University of Cambridge which provides no-fault compensation. This means that for non-negligent harm, you may also be entitled to make a claim

What will happen to the results of the research study?

The results of the research will be shared with the wider scientific community. The study researchers will achieve this by presenting their work at scientific conferences and in scientific journals. Our goal is that the knowledge gained from this research will benefit people such as yourself in the future. Results are presented in an anonymous format with all study participants combined. Neither you nor anyone else will be able to identify individuals in the results. Results will also be published on the EU Clinical Trials Register website, a central registry for all clinical trials conducted in the EU.

Anonymous datasets from the trial may also be made available to other researchers in line with national and international data transparency initiatives.

If you would like to obtain a copy of the published results, please contact your surgeon directly who will be able to arrange this for you.

Who is funding the trial?

The trial is being funded by the UK National Institute for Health Research.

Who has reviewed the study?

All research within the NHS is reviewed by an independent group of people called a research ethics committee. This process is designed to scrutinise the study design to ensure that it is appropriate and protects the interests of participants. This trial has been reviewed and given favourable opinion by Yorkshire & The Humber - Sheffield Research Ethics Committee.

Who is leading this study?

The study is being led by the Division of Neurosurgery, Department of Clinical Neurosciences, Addenbrooke's Hospital, University of Cambridge.

What assessments will be undertaken and when?

DCM can cause a wide range of problems and these all need to be measured to answer this question. This includes hand, arm and leg function, pain, quality of life and imaging (such as MRI or X-Rays). Some assessments will be performed by your clinical team, some will be performed by you (e.g. standard questionnaires) and some using a telephone conversation. This telephone conversation will be with a trained professional and member of the study team, who doesn't know you. This will enable them to make an assessment of your disease without knowing what treatment you have had – this is called 'blinding' and will increase the confidence in the results of the study. **It is important you do not reveal to them which treatment you have had.**

The types of assessments that will be performed, by whom and when is summarised below.

Who?	Start	Time of Surgery	6 Months After	12 Months After	24 Months After
You	Pain Quality of Life Mental Health Arm/Leg Function NHS Usage	Pain Quality of Life Mental Health Arm/Leg Function NHS Usage	Pain Quality of Life Mental Health Arm/Leg Function NHS Usage	Pain Quality of Life Mental Health Arm/Leg Function NHS Usage	Pain Quality of Life Mental Health Arm/Leg Function NHS Usage
Your Local Clinical Team	Medical History Medication History Arm/Leg Function Pain Neck X-Rays	Operation Details Change in Medication	Change in Medication Neck X-Rays	Change in Medication Neck X-Rays	Change in Medication Neck X-Rays
A member of the central trial team, unknown to you (by telephone)	Arm/Leg Function		Arm/Leg Function	Arm/Leg Function	Arm/Leg Function

In total, the questionnaires take about 30 minutes to complete, and the telephone assessment 15 minutes. These can be performed and arranged at your convenience.

Optional and Additional Assessments

If you own a compatible mobile phone (e.g. Apple or Google Android based device), you will also be invited to use an App called MoveMed, which has been designed to monitor your DCM more frequently, using simple tests that you can do on your phone, such as finger tapping. This will provide the researchers and your clinical team with a more complete picture of any ups and downs in your symptoms, which may not be obvious from your 6 monthly/yearly clinic assessments. There is a separate information sheet describing MoveMed in more detail.

We know from previous studies that supporting somebody with DCM can be challenging. With your consent, we will therefore also ask any carers or supporters that you may have, such as your partner or spouse, to complete a questionnaire called the CarerQol, to understand the effects that your DCM has on their life. There is a separate information sheet and consent form for CarerQol.

Further information and contact details

If you would like more information or wish to discuss any aspect of this study then please call one of the research team at any time, …….. or ……. on the numbers below.

If you have any concerns about the study you may approach your local Patient Advice and Liaison Services (or equivalent) for independent advice [details to be provided locally].

In the event of an emergency please contact:

[Details to be added for local contacts]

If you have more questions about this study, please contact any of the researchers listed below.

PI
Position
Email address

Clinical fellow or Research nurse
Position
Email address

General information

General information on medical research can be found on the NHS choices website.
http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx

Information on how and researchers need and use health information can be found here:
https://vimeo.com/264239790

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POLYFIX-DCM PARTICIPANT CONSENT FORM - TELEPHONE

Participant Number: _____ Time of consent (24-hour clock): _____

Please initial the box, with the participant's initials, to confirm they have agreed to each statement

1	I have read and understood the Participant Information Sheet – Telephone Version 1.0 dated 07/07/2022 for the above study, and I confirm that the study procedures and information have been explained to me over the phone and I understand this. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.	
3	I understand that personal information about me will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence and none of my personal data will be published.	
4	I understand that sections of my medical notes or information related directly to my participation in this study may be looked at by responsible individuals from the sponsor organisations, regulatory authorities and research personnel and that they will keep my personal information confidential. I verbally give permission for these individuals to have access to my records.	
5	I understand my GP will be informed of my participation in this study and sent details of the trial. I understand that the study team may contact my GP to obtain health status information if I am uncontactable for the study follow-up.	
6	I understand that my name, gender, date of birth, postcode, and NHS/CHI number will be used to access my central healthcare data that are held and maintained by the national health record organisations to provide information about my health status as part of this trial. I understand that, if they live in Wales, Scotland, or Northern Ireland, this information will be obtained from the equivalent sources described.	
7	I understand that my personal data might be transferred between the trial team at different trial sites in relation to my participation in this trial. I understand that any personal data will be sent using secure, encrypted mail servers.	
8	I understand that the data from this study, suitably anonymised, may be used in scientific publications, presentations and other research studies on DCM.	
9	I understand that the data from this study, suitably anonymised, may be shared anonymously with other academic and commercial researchers external to the project within the UK and beyond	
10	I have read and understood the compensation arrangements for this study as specified in the Participant Information Sheet.	
11	I understand that if I withdraw from the study, data collected up to that point may still be used in suitably anonymised form.	
12	I understand that the doctors in charge of this study may close the study or stop my participation in it at any time without my consent.	

13	I verbally agree to participate in this study.		
OPTIONAL		YES	NO
14	I verbally agree to complete the MoveMed digital assessments. I understand this involves placing an application on my mobile phone, which will send results, anonymously and encrypted, to the trial team.		
15	I would like to be contacted with a summary of the overall findings from this study.		
16	I verbally agree to long term follow up for an additional 5 years beyond the end of the study and for the collected data to be linked to the data collected during the study period. For example, this might include once yearly telephone assessments.		

_____

Name of patient (*to be completed by staff taking verbal consent*)

_____

Date participant verbally consented (*to be completed by staff taking verbal consent*)

_____ _____ _____

Name of person taking consent Signature Date

Witness Signature

When applicable: I attest that the above named participant received a verbal description of the study. This individual had sufficient time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

_____ _____ _____

Name of witness Signature Date

1 copy for the patient, 1 original for the Investigator Site File, 1 copy to be retained in the hospital notes.