PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

DISTRESSED Study

Does stabilisation following posterior decompression in Degenerative Cervical Myelopathy, reduce mechanical stress and spinal cord damage?

Information Sheet for Healthy Volunteers

We would like to invite you to take part in this research study as a healthy control subject.

1. What is the purpose of this study?

We would like to gain a better understanding of a spinal cord disease called Degenerative Cervical Myelopathy [DCM]. DCM is caused when wear and tear arthritis in the neck stresses and injures the spinal cord.

2. Why do we need controls?

There is an international trial taking place to compare two different types of treatment for DCM.

This will be decided by measuring many different aspects of the disease. This includes Magnetic Resonance Imaging [MRI] to calculate the shape and health of the spinal cord.

This form of MRI is very detailed, and this means that tiny changes to the settings of a MRI machine will change the numbers produced. This could create a problem when comparing people with DCM from one machine to another; as we would not know if the difference is due to the disease, or just due to the machine's settings.

We are therefore looking for healthy volunteers to help 'calibrate' the MRI machines being used for this trial. By calibrate, we mean to understand if and how one hospital's MRI machine is different to another hospitals. Once we know this, we can account for this in the main study's analysis.

3. What will happen to me if I take part*?*

We would like you to attend XXXXX for a MRI scan. This appointment can be arranged at your convenience. As you will be in a magnetic field we need to make sure there is no metal inside you that is unsafe to be placed inside a MRI. Before the scan we will check that you have no metal in your pockets or jewellery on. The scanner is noisy so you will be given ear protection. You will be lying flat, with your head resting on a small foam pad and be asked to stay still whilst the images are being taken. The MRI scan takes up to 45 minutes. **Any travel costs you face in order to take part in this study can be reclaimed.** Your imaging will be sent to the University of Cambridge for analysis, which is leading this study.

4. What are the possible risks/side effects of taking part?

There are no known side effects from having a MRI scan. Information collected as part of this study will be handled safely and securely, please see below.

5. How will we use information about you?

We will ask for your contact details, in order to follow up with you if your MRI reveals any abnormal findings of concern (see below, section 9).

Otherwise, only your MRI and age will be stored and shared with the researchers for this study. You will not be identifiable from this information.

6. What happens at the end of the study?

At the end of the study we will analyse the results and publish our findings in scientific journals. At this point, we will also get in touch with you and tell you what the results of the study were, if you wish.

Once we have finished the study, we will keep some of the data so we can check the results. This will be held securely for up to 5 years. We will write our reports in a way that no-one can work out that you took part in the study.

Fully anonymous datasets from the study may also be made available to other researchers in line with national and international data sharing and transparency initiatives, to support other research in the future. This may include academic or commercial researchers external to the project within the UK and beyond.

7. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

8. Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
  or by contacting the research sponsors directly:

9. Will my GP be informed?

Your GP will not be routinely informed if your participation in this study has been as a normal volunteer.

However, like faces, brains and spinal cords come in all shapes and sizes, so that there are many normal variations of what the scan shows. There is a chance of less than 3:100 that your MR scan may show a significant abnormality of which you are unaware. In such circumstances, you will be appropriately counselled by a medical specialist. You will be referred to the appropriate specialist in consultation with your General Practitioner *if that is what you would like*. Such early detection has the benefit of starting treatment early but, in a small number of cases, may have implications for future employment and insurance. We must notify you of any abnormal findings we notice on the scan you are undergoing, thus if you would not want to know these, we would recommend you do not take part in the study.

10. Are there compensation arrangements if something goes wrong?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Foundation NHS Trust but you may have to pay your legal costs.

Clinical Trials insurance has been obtained for the design of the protocol through the University of Cambridge.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS) at the hospital (tel: XXXXXX) or online at XXXXXXX.

11. Withdrawing from the study

Should you agree to taking part in this research study, you can withdraw at any stage without explanation and without affecting your current or future treatment. However your rights to access, change or move your information are limited, as data may already have been used to inform research findings (Please see information above). Consequently any data **already collected and analysed** will continue to be used in the study analysis. To safeguard your rights, we will use the minimum personally-identifiable information possible.

12. Local contact for information

If you would like further information please contact XXXXX (XXXXXX), Principal Investigator for this study.

Thank you for considering taking part in our study.

Study Title: Does stabilisation following posterior decompression in Degenerative Cervical Myelopathy, reduce mechanical stress and spinal cord damage?

Principal Investigator: XXXXX

Participant Number: _____

If you agree with each sentence below, please initial the box		**INITIALS**	
1	I have read and understood the Participant Information Sheet version XXXXXX for the above study, and I confirm that the study procedures and information have been explained to me. 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 images or information will be transferred to Cambridge University Hospitals for analysis.		
4	I understand that the data from this study, suitably anonymised, may be used in scientific publications, presentations and other research studies on DCM.		
5	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		
6	I understand that my MRI may reveal an unexpected and/or abnormal finding, and that in this case I will be contacted by the investigators		
7	I understand that if I withdraw from the study, data collected up to that point may still be used in suitably anonymised form.		
8	I give my consent for my GP to be notified regarding my participation in this study if required		
9	I agree to participate in this study.		
OPTIONAL		**YES**	**NO**
1	I would like to be contacted with a summary of the overall findings from this study.		

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

Time of Consent (24hr clock) _____:_____

PARTICIPANT INFORMED CONSENT FORM

Study Title: Does stabilisation following posterior decompression in Degenerative Cervical Myelopathy, reduce mechanical stress and spinal cord damage?

Principal Investigator: XXXXX

Participant Number: _____

If you agree with each sentence below, please initial the box		**INITIALS**	
1	I have read and understood the Participant Information Sheet version XXXXXX for the above study, and I confirm that the study procedures and information have been explained to me. 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 images or information will be transferred to Cambridge University Hospitals for analysis.		
4	I understand that the data from this study, suitably anonymised, may be used in scientific publications, presentations and other research studies on DCM.		
5	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		
6	I understand that my MRI may reveal an unexpected and/or abnormal finding, and that in this case I will be contacted by the investigators		
7	I understand that if I withdraw from the study, data collected up to that point may still be used in suitably anonymised form.		
8	I give my consent for my GP to be notified regarding my participation in this study if required		
9	I agree to participate in this study.		
OPTIONAL		**YES**	**NO**
1	I would like to be contacted with a summary of the overall findings from this study.		

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

Time of Consent (24hr clock) _____:_____