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Optimising diagnosis and prediction of outcome of spinal surgery using diffusion tensor imaging and machine learning

Research Patient Information Sheet (surgical patients)

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Invitation

You are being invited to take part in a research study. Before you decide it is important for you to understand why the 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 there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Our main aim is to develop an imaging technique to help us measure more accurately the narrowing of the space within the spine and the damage to the nerves in the lower spine in people with low back pain. The information gained from this technique will help to improve the diagnosis and predict the outcome of spinal surgery.

Why have I been chosen?

You are someone who has low back pain and are going to undergo a surgical procedure on your spine. The decision to offer surgery has been part of your normal care and is unconnected with this study.

The assessments to be performed as part of this study will allow us to assess the relationship between the physical changes (e.g. narrowing of spaces in the spine carrying nerves as well as nerve compression) and symptoms (e.g. amount of pain), and allow us to understand the extent to which the spinal surgery may be successful.

Do I have to take part?

No. It is entirely up to you. If you would like to take part, you will be asked to sign a consent form. Even after you have signed this consent form and agreed to join the study, you are free to withdraw from the study at any time. If you decide not to take part, or withdraw from the study, it will not affect your current or future treatment by this department in any way.

What will happen to me if I take part?

Once you have decided to take part in this research, a member of our research team will discuss the study with you and answer any questions you may have by telephone or in person. If you are still happy to take part, you will be invited to the Nick Davey laboratory, located in Charing Cross hospital, at a convenient time to sign the consent form.

There are two parts to this study. In part one, you will need to complete some questionnaires that will ask you about your symptoms, handedness and daily activities. We will also record basic information (e.g. date of birth, body height, body weight). We will assess your existing MRI scans which have been carried out as part of your routine clinical care.

In part two, you will receive a full assessment before and 3 months after your surgical procedure. The assessments will include another MRI scan called diffusion tensor imaging (DTI) in Imperial College Clinical Imaging Facility at Hammersmith Hospital and a neurophysiological assessment at the Nick Davey laboratory at Charing Cross Hospital. These two assessments could take place on the same day or on different days.

The DTI is to assess the damage to the nerves of your lower spine and the procedure will be the same as that of your previous MRI scan performed as part of your routine health care. This part of the assessment will take no longer than 60 minutes.

The neurophysiological assessment is to measure the way the brain controls voluntary movements of your leg muscles. To do this we will use an investigative procedure called transcranial magnetic stimulation (TMS). This is used to activate the nerves in your brain which control your leg muscles and involves placing a plastic coil in a specific position over your head, this is connected to a machine which delivers a small magnetic stimulus to the nerves in the brain, this is not painful and does not involve any needles. A number

of pulses will be given while you contract your muscles by lifting your toes or pressing your toes towards the floor. We will record the electrical activity from the muscles under study in response to these stimuli. Recordings of your muscle activity will be made using sticky self-adhesive electrodes (like those used to record ECGs) stuck to the skin overlying the muscles. The relation between the stimulus and the responses in the muscle will be analysed by computer. This part of the assessment will take no longer than 90 minutes.

You will need to answer some questionnaires that will be asking you about your symptoms, handedness and daily activities post-op at 1month, 2month and 3months via telephone, post or email.

What are the side effects, and are there any risks in taking part?

The assessment techniques are safe and non-invasive and there are minimal risks from having these test performed under strict safety guidelines which include stringent exclusion criteria (detailed at the end of the form and in the screening questionnaire). All tests will be performed within your limits of tolerance. You may feel a mild discomfort from the removal of the sticky electrodes from the skin, this will be minimised by skin preparation before the experiment. You may experience claustrophobia when undergoing the MRI scan, steps will be taken to minimise this including a hand-held "help" button for the duration of the scan.

What are the possible benefits of taking part?

There are no clear benefits to you from taking part. However, the information we get from this research might help in the future with diagnosis of spine disease. It also may help predict the outcome of surgery by looking at the results of pre-surgical assessments. It may also help in the management of a patient treatment process.

Will my taking part in this study be kept confidential?

Any information you give us will be kept strictly confidential. If the study is published in a book or scientific journal, no individual will be identified in anyway.

What if something goes wrong?

In the extremely unlikely event that anything goes wrong while you are taking part, local hospital facilities are available (A&E department), as well as an emergency assistance telephone number.

Imperial College London holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr Paul Strutton, 0203 313 8837 or email: p.strutton@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

What will happen to the results of the research study?

The results of the study will be analysed by the research team and presented at health care conferences and published in scientific journals. No individual subject will be identified in any report or presentation arising

from the research. If you would like to receive the results of the study when completed, we are happy to send it to you electronically as an email or by post.

The results of the questionnaires are going to be compared with those from a group of patients who are not going to be having spinal surgery.

Who is organising and funding the research?

This research is being funded by Imperial College London and the Wellcome Trust. The study will be run by a research team based at Imperial College, London.

Will I be paid for taking part in the study?

You will not be paid for your participation in the study, but we will pay for your travel expenses to Charing Cross Hospital and Hammersmith Hospital. Please keep the receipts for your journey as these will be required for your reimbursement.

Who has reviewed the study?

This study has been approved by the NRES Committee London - Fulham.

Contacts for further information:
If you would like to consider this study further before you make your decision, please take your time to do so. You may ask for further information by telephoning 020 3 313 8837, which has a 24-hour answer phone. The person to speak to is the investigator, Dr Paul Strutton, Dr Chloe Chiou, or the clinical trial coordinator, Mr David Egbosimba (d.egbosimba@imperial,ac,uk). You may also send an email to p.strutton@imperial.ac.uk to request further information.

Inclusion:
1) Participants with diagnosed lumbar nerve compression, as confirmed with MRI.
2) Participants must be above 18 years of age.

General Exclusion criteria:
1) Participants who suffer from any neurological conditions.
2) Participants who have had spinal surgery or complex spinal disease.
3) Pregnancy (or possibility thereof) or breast-feeding

Criteria for exclusion from TMS and MRI:
If you:
1) Have a history of epilepsy (fits or seizures) or a family history of epilepsy (for TMS only).
2) Have any metal implants or an artificial cardiac pacemaker.
3) Have had previous brain surgery (for TMS only)
4) Are currently on antidepressants or other neuromodulatory drugs (for TMS only).