To be presented on local headed paper

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Octopus Clinical Trial Magnetic Resonance Imaging (MRI) Setup

We are inviting you to take part in the MRI setup as part of the Octopus study.

Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.

- You are free to decide whether to take part in this research procedure. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part, you will be given a copy of this information sheet and asked to sign a consent form. You'll get a copy of that as well.

Important things that you need to know

- We want to ensure that the MRI scanners and procedures for handling and sending medical images are standardised to be able to compare MRI results from the hospitals that participate in the Octopus study.
- We are inviting you to take part in the setup as a person with multiple sclerosis (MS) or a healthy volunteer.
- There are no known harmful effects from the strong magnetic field used for the MRI.
- This procedure will require you to visit the hospital once to conduct the MRI scan.

Contents

How to contact us

If you have any questions about this study, please talk to your doctor or nurse:

Name of doctor or nurse
Hospital Department
Hospital
Address
Address
Tel: XXXXX XXX XXX

1 Why are we doing this study?

Your hospital is taking part in a study called Octopus which involves Magnetic Resonance Imaging (MRI). We need to ensure that the MRI scanners and procedures for handling and sending of medical images of the brain are standardised, to be able to compare MRI results from the hospitals that participate in this study. To do this, we are asking each participating hospital to send MRI brain scans of a volunteer (healthy volunteer or patient) to a central MRI reading centre at UCL. The test MRI does not include an injection. Injections are something used in these scans to increase the contrast of the structures and fluids visible on the image. At UCL, the scans will be assessed to ensure that the pictures taken by the MRI machines are of good quality and meet the needs of the study.

Each site is normally only required to obtain one setup scan per MRI machine as part of their study approval. However, if the quality of the initial MRI is not good enough, if some settings need to be changed or if there were a scanner upgrade, the process will need to be repeated.

2 Why am I being asked to take part?

You are being asked to take part in the Octopus MRI setup as a volunteer, who may be willing and able to have an MRI scan of the brain.

3 What will happen to me if I take part?

Magnetic resonance imaging is a procedure that uses a magnetic field to take a special picture, in this case, of the brain.

During the MRI examination, you will lie on a table inside a cylindrical machine.

The space inside the machine is small. You must not move during the procedure. Special supports will keep your head from moving. Although you may not talk during the MRI procedure, you will be able to communicate with the MRI technician by pressing a call button, that will be within your reach. The technician will observe you during the entire time that you are in the MRI machine, up to 30 minutes.

4 What are the possible benefits of taking part?

We hope that by taking part in this MRI setup, you will help set-up the Octopus trial at your site. The Octopus trial will assess a number of treatments that may slow the progression of people with multiple sclerosis.

There are no direct benefits to you from taking part in this procedure.

5 What are the possible disadvantages and risks of taking part?

There are no known harmful effects from the strong magnetic field used for MRI. However, the magnet is so powerful that it can send unsecured metal objects flying across the room. Additionally, the magnet may affect pacemakers, artificial limbs, and other medical devices that contain iron, e.g. by warming up metal parts. There is a risk that metal objects coming near the magnet may become dangerous as they are pulled toward the magnet. You will be asked to remove any metallic objects before entering the MRI facility.

If you may have metal fragments in your eyes, an MRI can cause damage to the retina. If there is a concern about possible metal fragments in the eye (e.g. working as a welder), you should inform the investigators before any MRI scan.

Iron pigments in tattoos or tattooed eyeliner can cause skin or eye irritation.

Because MRI acts like a magnet, people with any of the following cannot participate in this procedure:

- metallic foreign bodies in the eye
- cardiac pacemakers
- clips in the central nervous system
- automatic internal cardiac defibrillators
- implanted infusion pumps
- implanted insulin pumps
- bone growth stimulators
- non-removable neurological stimulators
- cochlear implants
- shrapnel

Pregnant women, or those who plan to start a pregnancy soon, should not participate in this procedure. Although the strong magnetic field used for a MRI test does not appear to be harmful, an MRI is not usually done during pregnancy.

Some people may experience claustrophobia or discomfort from being in a confined space. MRI scanners can be noisy at times. This is normal and not harmful. You will be given earplugs to wear. Lying on the MRI table without moving may be uncomfortable. Motion affects the MRI accuracy. You may not be a suitable candidate if you are unable to remain still during the MRI procedure.

People weighing more than 285 pounds (130kg), or who have claustrophobia should not participate in this procedure.

6 What happens if I don't want to participate in the set-up procedure?

Your participation in this procedure is entirely voluntary.

You may choose not to participate in this procedure or decided to withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

7 More information about taking part

Will I get back any travel costs?

Reasonable travel costs may be claimed for your participation i.e. standard class travel.

How will my personal information be used?

University College London (UCL) is the sponsor for this study, based in United Kingdom. University College London (UCL) will be using MRI scans to undertake this study and will act as data controller for this study. The MRI scans sent to UCL are anonymised and contain no identifiable information about you.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate.

If you withdraw from the MRI set-up we will keep the information about you that we have already obtained.

How will my personal information be stored and collected?

Your personal data will be collected and stored by the following organisations:

- The hospital where the MRI setup is being conducted.
- Institute of Neurology (ION) at UCL who are leading on the MRI aspect of the Octopus study will only receive information that will not allow you to be directly identified.

Your hospital will collect information from you and your medical records for this study in accordance with our (UCL) instructions.

Your hospital will keep identifiable information about you from this study for at least 25 years after the study has finished.

Your hospital will use your name, NHS/CHI number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded, and to oversee the quality of the study. UCL will collect information (your MRI scan) about you for this research study from your hospital. This information will include health information, which is regarded as a special category of information. We will use this information to conduct our research. Individuals from UCL, regulatory organisations or from the NHS Trust, may look at relevant sections of your medical notes and data collected during the study, where it is relevant to you taking part in this research. This is to check the accuracy of the research study. This information is held in compliance with the UK General Data Protection Regulation (GDPR).

Your hospital will keep your name, NHS/CHI Number and contact details confidential and will not pass this information to MRC Clinical Trials Unit at UCL.

Where information could identify you, the information will be held securely with strict arrangements about who can access the information. The people who analyse the information will not identify you.

Who is organising and funding the study?

Octopus is organised by the MRC Clinical Trials Unit at UCL, which has run studies for many years.

The study coordination, data collection, analysis and administration will be provided by the MRC CTU at UCL. You can find out more about us at https://www.mrcctu.ucl.ac.uk/. The MRI collection and review will be performed by the UCL ION.

Your study team are not receiving any money or other payment for asking you to help in this set-up.

University College London (UCL) has overall responsibility for the conduct of the study. We are responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

The study is funded by a grant awarded by the MS Society with further funding from UCL.

Who has reviewed the Octopus study?

The study has been reviewed by international scientists and other doctors and experts in the field of multiple sclerosis and its treatment. It has been approved by London - Hampstead Research Ethics Committee and the Health Research Authority (HRA).
It has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA), as well as by the independent NHS research ethics committee and your hospital's Research and Development Office.

The Integrated Research Application System (IRAS) ID for the study is 1003943.

What if something goes wrong for me?

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence, then you may be able to claim compensation.
After discussing with the study doctor, please make the claim in writing to Professor Jeremy Chataway, who is the Chief Investigator for the Octopus study and is based at UCL. The Chief Investigator will then pass the claim to the Sponsor and on to Sponsor's Insurers. If you have a claim, then it might be helpful to consult a lawyer. Participants may also be

able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of UCL or another party.

You should discuss this possibility with the study doctor in the same way as above.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the clinical trial/study, the normal National Health Service complaints mechanisms are available to you. Please ask your clinical trial/study doctor if you would like more information on this. Details can be obtained from the NHS website. You can also contact the Patient Advice and Liaison Service (PALS) or Patient Advice & Support Service (PASS) at your local site. They can offer confidential advice, support and information based on your concerns.

8 Contacts for further information

If you want further information about the Octopus study for which this procedure is being used to set up, information is available on our website www.ms-octopus.info. Please also contact your local study team (see below).

Name of contact
Hospital Department
Hospital
Address; Address
Tel: XXXXX XXX XXX

Thank you for taking the time to read this information and for considering having this procedure to help the Octopus study. Please feel free to keep this information sheet.

If you decide to take part in this procedure for Octopus, you will be asked to sign a consent form and you will be given a copy of the signed consent form to take home.