To be presented on local headed paper

Octopus Clinical Trial: Collecting Information About a Participant or Participant's Partner's Pregnancy

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 provide this information.

- You are free to decide whether you would like to provide information on your pregnancy. It will not affect your care from your own doctors, or from the study doctors if you are a participant, if you choose not to provide any information.
- Your or your partner's hospital and University College London (UCL) will not share information with others that can identify you.
- 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 provide information on your pregnancy, 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 are currently unsure if the trial treatments you or your partner has been taking have any effects on fertility and pregnancy.
- We want to collect information about your pregnancy and the health of your baby. We would like to continue to follow the health of your baby for 30 days after birth.

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How to contact us

If you have any questions about the Octopus study or this request for information, please talk to your partner's doctor or nurse:

Name of doctor or nurse
Hospital Department
Hospital
Street
City/Town,Postcode,
Tel: XXXX XXX XXXX

1 Why am I being asked to provide information?

You or your your partner is participating in a research study called Octopus. Octopus aims to find new treatments for people with progressive multiple sclerosis (PMS) that will slow down the rate of disability worsening. In addition to the standard treatment, there are 3 possible treatments that your partner may be taking:

- Arm A: a placebo (or dummy drug)
- Arm B: R/S-Alpha Lipoic Acid (R/S ALA)
- Arm C: Immediate release metformin

When you or your partner joined the study, you/they agreed to use birth control methods while taking the Octopus treatment because the effects on pregnancy and fertility are currently unknown.

You or your partner has reported that you have become pregnant. The study team at the Medical Research Council (MRC) Clinical Trials Unit (CTU) at UCL would therefore like to collect information about your pregnancy and the health of your baby.

2 What will I need to do if I agree to provide information?

If you agree to provide information, you or your partner's doctor will request details about your pregnancy and the health of your baby.

We would like continue to follow the health of your baby for 30 days after birth to monitor for the unlikely chance of any significant medical issues.

This information will be provided to the MRC CTU at UCL to support efforts to monitor the effects of the trial treatment and to submit reports, as required under law, to the Regulatory Authorities.

3 What are the possible benefits of providing information?

You will not benefit directly from allowing the MRC CTU at UCL to follow the progress of your pregnancy and the health of your baby. However, the information we get from this study will improve our understanding of the effects of the Octopus treatments during pregnancy and the health of your baby.

4 What are the possible disadvantages and risks of providing information?

As with data collection, there is the possibility of breach of confidentiality. Every precaution will be taken to secure your personal information to ensure confidentiality.

If you are the partner of an Octopus participant and you agree to provide information, it will be stored under your partner's study identification number. This number will be used on data collection forms and in the database. No names or private information will be provided to the MRC CTU at UCL. Please refer to **Section 5** "How will your data be collected and stored?" for further information.

5 Do I have to provide this information?

No, your participation is entirely voluntary. It is up to you to decide to allow the MRC CTU at UCL to collect information about your pregnancy. If you decide to take part you will be given this participant information sheet to keep and you will be asked to sign a consent form. A decision to not take part at any time will not affect the care you or your baby will receive.

If you are a participant on the Octopus study, you must stop your Octopus treatment, but can remain in the trial, unless you choose to withdraw. Information on withdrawal from the Octopus trial can be found in the Participant Information Sheet that was given to you when you were first contacted about the study, and which should also be with your copy of the consent form.

How will my personal information be used?

UCL is the sponsor for this study, based in the United Kingdom. UCL will be using information from you and your medical records in order to collect details about your pregnancy and the health of your baby and will act as data controller for this study. UCL will be responsible for looking after your information and using it properly and will keep information about you for 25 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from providing this information, we will keep the information about you that we have already obtained. To safeguard your rights, we will not use the minimum personally identifiable information possible and only your or your partners participant ID number. You can find out more about how we use your information at www.ctu.mrc.ac.uk/general/privacy-policy

How will your data be collected and stored?

Your or your partner's hospital will collect information from you and your medical records for details about your pregnancy and the health of your baby in accordance with our instructions.

Your or your partner's hospital will use your name, NHS/CHI number and contact details to contact you about details about your pregnancy and the health of your baby.

The hospital will make sure that relevant information about your pregnancy and the health of your baby is recorded for your care, and to oversee the quality of the study. UCL will collect information about your pregnancy and the health of your baby for this research study from your or your partner's hospital. This information is held in compliance with the UK General Data Protection Regulation (GDPR).

Individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the data collected.

Your or your partner's hospital will keep your name, NHS/CHI Number and contact details confidential and will not pass this information to MRC CTU 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 be able to identify you. Your or your partner's hospital will keep identifiable information about your pregnancy and the health of your baby for this study for at least 25 years after the study has finished.

When you agree to take part in a research study, the information collected about your health and care may be provided to researchers running other research studies in UCLand in 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 relevant legislation, ethics and NHS research policy requirements.

The hospital and UCL will not share information with others that can identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your or your baby's care. It will not be used to make decisions about future services available to you, such as insurance. If there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Who is organising and funding the study?

The Octopus study is organised by the MRC CTU at UCL, which has run studies for many years. The study coordination, data collection and analysis and administration will be provided by the MRC CTU at UCL. You can find out more about us at www.ctu.mrc.ac.uk.

Your or your partner's study doctor or neurologist are not receiving any money or other payment for asking you to collect information about your pregnancy and the health of your baby as part of the study.

The MRC CTU at 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 supportive 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 authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) as well as by an independent NHS research ethics committee (London - Hampstead Research Ethics Committee) and your or your partner's 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 your or your partner's study doctor, please make the claim in writing to Professor Jeremy Chataway, who is the Chief Investigator for the clinical trial and is based at UCL. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Participants may also be able to claim compensation for injury caused by participation in this clinical trial without the need to prove negligence on the part of UCL or another party. You should discuss this possibility with your 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 or your partner's participation in the clinical trial, the normal National Health Service complaints mechanisms are available to you. Please ask your or your partner's study doctor if you would like more information on this. Details can also 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.

6 Contacts for further information

If you would like further information about the Octopus study, information is also available on our website: www.ms-octopus.info.

Please also contact your or your partner's study doctor or nurse: (see below).

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

Thank you for taking the time to read this information. Please feel free to keep this information sheet.

If you decide to provide information on your pregnancy and the health of your baby to the Octopus trial, you will be asked to sign a consent form and you will be given a copy of the signed consent form to take home.