Oxford University Hospitals
NHS Foundation Trust

Local Investigator: Dr Sam Mathewlynn Contact details: 07955 434639

PARTICIPANT INFORMATION SHEET

Oxford Placental UltraSound (OxPLUS) Study

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask the research team.

What is the purpose of the study?

The placenta (sometimes called the 'afterbirth') works as the baby's 'life-support system' enabling them to grow to their full potential. Unfortunately, sometimes the placenta does not work as well as it needs to. When this happens, the baby does not grow as well as it should, which can lead to problems and sometimes, even to the loss of the baby. This study aims to see if a new piece of computer software, called the 'OxNNet toolkit' can predict which babies will not grow as well as they should using the information gained from the 3D ultrasound scan about the size of the placenta and its blood flow, together with other known risk factors. This may be used in the future as a screening test for all pregnancies, to identify when the baby may be at risk. This will allow issues to be identified much earlier so that babies at risk of not growing properly can be monitored more closely.

Why have I been invited?

You have been invited because you are due to attend your routine 11-14 week pregnancy scan. We are planning to involve 3500 pregnant women aged 18 years or above who are in the first few months of pregnancy and attending their routine 11-14-week ultrasound at the John Radcliffe Hospital, Women's Centre.

Do I have to take part?

No. Participation is entirely voluntary and if you decide not to take part, your decision will have no effect on your appointment or any future care. If you decide to take part, you are free to withdraw from the study at any time without giving a reason.

What will happen to me if I decide to take part?

A single visit will happen alongside your routine clinical appointment. The steps described below are anticipated to add approximately 10 minutes to your routine appointment time.

Eligibility Check and Consent Process

During your appointment, you will be asked if you would like to undergo first trimester combined screening as part of your routine first trimester pregnancy scan. The combined screening test is an optional addition to the usual 'dating' scan and involves taking a blood sample to analyse for potential genetic abnormalities such as Down's syndrome. If you choose to undergo this screening, you will be eligible to take part in the OxPLUS study.

If you would like to take part, you will be asked if you have read and understood this leaflet and will be given more time to consider taking part if you need it. You will then be asked to sign a consent form to confirm your participation. The OxPLUS study only involves one ultrasound scan which will be done at this visit. No other visits will be required and the researchers will follow up the outcome of your pregnancy from your notes after you deliver.

Medical History

We will ask a few questions regarding your medical history for example if you have high blood pressure (BP) or diabetes.

Basic Measurements

We will record your BP in both arms, a carbon monoxide reading and your height and weight.

Ultrasound Scan

You are having an ultrasound scan; if you take part in the study this will be about 3-4 minutes longer. This extra scan is only of your placenta not your baby and will not be used for any clinical purpose.

Blood Tests

You will have a blood sample taken as part of your routine care. If you agree to help us with this research, we will use some of the blood left over from your sample to run an extra test for Placental Growth Factor (PlGF). The result of the PIGF test is one way doctors can try and predict if a baby will not grow as well as it should. We will use this result along with the results of the 3D ultrasound scan to see if we can develop a screening test for use in the future, to identify when a baby may be at risk.

Follow up

After you have birthed your baby, the research team will access your pregnancy records to collect information about any hospital appointments you have had during your pregnancy and to find out the outcome of your pregnancy. Please note, this does not require you to attend for any further appointments.

What should I consider?

You should consider whether you are willing to spend approximately an extra 10 minutes at your routine ultrasound appointment and are happy for the collection of information to take place once you have given birth. If you are participating in any other research study, you will still be able to be in this one.

Are there any possible disadvantages or risks from taking part?

You will be required to spend a bit more time than usual in clinic to allow the research to take place.

Ultrasound
Ultrasound has no known risks in pregnancy and all of your scans will be performed after the most sensitive period of pregnancy is completed. Furthermore, the extra scan will be of the placenta, and will not involve your baby.

Blood tests
Having blood taken can be uncomfortable and can cause bruising and/or fainting so, the blood test needed for the study will be taken when you have your normal routine blood taken for the other standard screening.

What are the possible benefits of taking part?

There is no direct benefit for this pregnancy. This research will help to develop a new screening tool for babies at risk of not growing well. We hope this will improve the care of unborn babies in the future.

Will my General Practitioner/family doctor (GP) be informed of my participation?

We will not inform your GP about your participation in this study as your involvement will not affect your clinical care in any way. You are however free to discuss your participation with your GP or any other health professional involved in your care.

Will my taking part in the study be kept confidential?

Yes. The local research team will collect information concerning you as part of the study and will be able to identify you. However, they have a duty of confidentiality towards you and will only use your information as outlined within this leaflet. All information that is recorded during your participation for

the purposes of the study including any scans, tests or data will be coded with a study identification number (study ID) so that you cannot be identified from it by anyone other than the research team. The research team will maintain a document which contains your study ID and contact details, but we will only link the information where necessary and to collect further data about the outcome of your pregnancy. The extra ultrasound scan will be transferred securely from the ultrasound machine to a University computer by a member of the research team to enable the images to be reviewed and the results to be included in the study database.

All information collected about you will be stored securely in a study database on password protected University computers which will be kept strictly confidential and only the research team will be able to access the information.

Responsible members of the University of Oxford and the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

No. You will not be paid for taking part in this study.

What will happen to the samples I give?

As part of your routine care you will provide a blood sample and for the purposes of this study a small amount of this sample will be used for the extra PlGF test. The analysis for both routine and study tests will be carried out by the local hospital laboratory with the sample destroyed soon after analysis according to the standard laboratory procedures.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom and is the data controller responsible for looking after your information and using it properly. We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for no more than 3 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study.

The local study team will use your name, contact details and NHS number to contact you about the research study, collect study data and to oversee the quality of the study. They will keep identifiable information about you from this study in keeping with local policy for retention of medical records.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting the research team using the details given at the end of this leaflet.

What will happen if I don't want to carry on with the study?

You are free to withdraw your consent to take part in this study at any time and for any reason. Your decision to withdraw will have no effect on your current or future care. If you withdraw from the study, any data collected for research purposes (including scans and results from blood tests) up until the time you withdraw will continue to be held and used for this research as outlined in this leaflet, unless you

state otherwise. To withdraw from the study, please contact the study team, whose contact details can be found at the end of this information leaflet.

What happens at the end of the study?

The research team aim to present the results at scientific meetings and in medical journals. You will not be identified and your personal and clinical details will remain strictly confidential. Any publication arising from the research will be available upon request to all participants. We would like keep the additional 3D ultrasound scan and clinical information for use in future research studies. These will be anonymised and no-one will be able to identify you from the scan.

Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis).

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Professor Sally Collins on 01865 851165 or sally.collins@wrh.ox.ac.uk or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480, or RGEA.Complaints@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please telephone 01865 221473 or email PALS@ouh.nhs.uk.

How have patients and the public been involved in this study?

A patient and public involvement (PPI) group has been involved in the design of this research and have provided input into the information presented in this leaflet to ensure that it is easy to understand and provides all the essential information needed to consider in taking part in the study.

Who is organising and funding the study?

This research study is organised by a research team based at the Nuffield Department of Women's and Reproductive Health at the University of Oxford. The study is sponsored by University of Oxford and funded by The Sir Jules Thorn Charitable Trust an independent charity that awards grants for the conduct of research.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by _____ Research Ethics Committee.

Further information and contact details:

Further information is available on the study website www.oxplus.info

Please contact Dr Sam Mathewlynn on 07955 434639 or e-mail oxplus@wrh.ox.ac.uk

If you would like more general information about taking part in research please follow the attached link

https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-take-part-in-a-study.htm

Thank you for considering taking part.