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Participant Information Sheet

Pregnancy Reference Ranges Study
(PREGRRS)

Chief Investigator: Professor Tricia Tan
Co-Investigators: Dr Rebecca Scott, Dr Bryony Jones

Introduction

We would like to invite you to take part in our study. Before you decide if you would like to participate, it is important to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. Please ask the study team if there is anything that is not clear or if you would like more information, and take time to decide if you wish to take part.

The first part of this Patient Information Sheet tells you the purpose of the study and what will happen to you if you take part. Afterwards we give more detailed information about the conduct of the study. Please do ask if anything is unclear.

What is the purpose of the study?

A woman's body changes through each trimester in pregnancy. This means the levels of many different hormones and other substances in the blood vary in pregnancy. Doctors, midwives and other people who look after pregnant women should use reference ranges for these blood markers that are specific to each trimester of pregnancy, and not just use the ranges used for the non-pregnant population. This is in line with international guidance. We are therefore asking healthy pregnant women to given a sample of blood or urine so that we

can provide up-to-date reference ranges for blood tests in pregnancy at Queen Charlottes' and Chelsea Hospital.

In particular we plan to make reference ranges for levels of different thyroid hormones. Thyroid hormone is vital for the neurological development of the baby, so ensuring that a mother's thyroid hormone levels are normal is essential. We will also measure urine iodine levels as these affect how the body makes thyroid hormones. We also plan to measure some blood pressure hormones (renin and aldosterone) and a heart marker (troponin). We know that more women are suffering from blood pressure problems and heart disease in pregnancy, so being able to diagnoses these accurately is really important for good care of the mother.

Do I have to take part?

No. Your participation is voluntary. If you decide not to take part, this will not affect the standard of care that you normally receive. If you do decide to take part, you are free to withdraw at any time and you do not have to give a reason.

Who can and cannot take part?

A woman can take part in the study if:

- She is over 18 years of age
- She is currently pregnant and has her antenatal care at Queen Charlotte's & Chelsea Hospital
- She has a singleton pregnancy

A woman cannot take part in the study if:

- She has a multiple pregnancy (2 or more babies in this pregnancy)
- Current or previous history of thyroid disorder
- Previous or current thyroid medication use
- Inability to understand and write in the English Language
- Unable to participate due to other factors, as assessed by the Chief Investigators

What happens if I do take part?

If you decide to take part we will first email you a link to a secure online consent form for the study. We will also send you a personalised link to a brief online questionnaire. This will ask a few questions about you, your pregnancy and your previous health. This would include your date of birth, ethnicity, gestation and estimated date of delivery, any history of thyroid disease, any other medical conditions and medications. The data for this will be collected

pseudonymously (i.e. with a unique study number but none of your personal details) and stored securely. This should take no more than 10 minutes.

Once you have completed the consent form and the questionnaire, we will arrange for you to come to give your samples. These will be 2 tubes of blood (a total of 20 ml) and/or a sample of urine (100ml) from you. This should take no more than 10 minutes. The blood can be taken at the same time as any other blood test you are having as part of your antenatal care, or at a separate time if you prefer. We would ask that you complete the consent and questionnaire at least 72hours prior to any visits to Queen Charlotte's and Chelsea Hospital so we can arrange for the sample collection. That is all the study involves.

The samples will be analysed for thyroid hormones directly within the laboratories at Imperial College Healthcare NHS Trust. Part of the samples will also be frozen and stored within specific freezers the biochemistry department at Imperial College Healthcare Trust NHS. The samples will be labelled pseudonymously. The team responsible for managing and securing these samples are experienced in the curation and care of biological samples. These frozen samples will subsequently be analysed for the other analytes such as renin, aldosterone and troponin, to produce other pregnancy-specific reference ranges. When we analyse the samples, if we find any concerning results, we will contact you to discuss the results. All samples will be kept for a maximum of 10 years in accordance with Imperial College policy.

Once we have all the study results, we will send an email to all participants explaining our findings.

As pregnant women are rarely included in any research studies, your participation is very much appreciated. On the consent form we will therefore ask that the questionnaire data and samples you give are used in other ethically approved studies, such as producing the troponin reference range studies. We will also ask if you are willing to take part in any other studies.

Are there any risks or discomforts?

All blood tests will be taken by very experienced clinicians or phlebotomists, but there is always a risk that having a blood test can be uncomfortable.

What are the possible benefits of taking part?

While we are going to analyse the samples pseudonymously (so that the samples will be identified by a unique code, but not your name, date of birth or hospital number), if we find a

notably abnormal result (as defined prior to the study), we will then break the pseudonymisation and contact you with the abnormal result, offer to discuss this with you and provided an appropriate follow on care plan for you in pregnancy and beyond.

Will I be paid?

There is no payment for participants in this study.

What happens when I stop taking part in the study?

When you stop taking part in the study you will not need to do anything further.

What will happen to the results of the research study?

The new reference ranges will be published so all clinicians looking after pregnant women will be able to use them. You will not be identified in any reports or publication.

Who is organising and funding the research?

The research project is organised by the Endocrinology and Obstetric teams at Imperial College Healthcare NHS Trust. The study is being funded by Abbott diagnostics.

Who has reviewed the study?

This study has been given a favourable ethical opinion for conduct in the NHS by the Cambridge South Research Ethics Committee.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will 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 Professor Tricia Tan. The normal National Health Service complaint mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team.

How will we use the information about you?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from you and your medical records for this research project. This information will include name, unique medical record number and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Legal Basis

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.
Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

International Transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed. In this study, the study protocol and results will be shared with the study funder Abbott Diagnostics; however all shared data will be anonymised.

Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

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. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. We will keep the samples you have given to provide other reference ranges for pregnancy.

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/
- by asking one of the research team
- by sending an email to imperial.pregrrs@nhs.net

Complaint

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

What will happen to the data?

Imperial College London and Imperial College Healthcare NHS Trust will keep identifiable information about you from this study for 10 years after the study has finished.

How can I get more information?

You can find out more about how we use your information from Dr Rebecca Scott on by e-mail at imperial.pregrrs@nhs.net