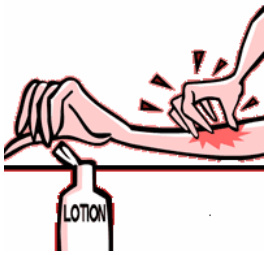
Imperial College London

THE METABOLIC PROFILE IN INTRAHEPTIC CHOLESTASIS OF PREGNANCY AND/OR GESTATIONAL DIABETES STUDY PATIENT INFORMATION SHEET



You are being invited to take part in a research study. Before you decide whether to take part 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 family and friends before you decide whether or not you would wish to take part. Ask us if there is anything that is not clear or if you would like more information.

The purpose of the study

We are interested in studying diseases of pregnancy that can affect the health of the mother and baby. In particular we are trying to understand what genetic and metabolic factors can make the mother unwell during pregnancy, and which of these can also make the baby unwell when in the womb. To date, we have been taking blood samples from women with diseases of pregnancy (including intrahepatic cholestasis of pregnancy (ICP)) to perform these studies. More recently it has been suggested that having ICP or other complications of pregnancy such as gestational diabetes mellitus (GDM) that are associated with elevated levels of lipids and glucose may have longer health term implications for women. In particular they may have an increased risk of developing cardio vascular disease or metabolic disease such as diabetes in later life. By investigating the levels of as lipids, glucose and hormones in women with ICP and other complications of pregnancy, including GDM, researchers hope to gain further insights into the causes of these conditions which in turn will help doctors to be able to advise women about future lifestyle choices they may want to make regarding areas such as diet.

Why have I been chosen?

We would like to invite you to join our study as a pregnant or non pregnant woman who has not had (or who is not expected to have) a pregnancy complicated by conditions such as ICP and/or GDM. Women who have uncomplicated pregnancies are often referred to as 'control' groups in research. We need to include them in the study to be able to compare any significant results we may find and ensure that they apply to the disease group women only.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. However, you are still free to withdraw from the study at any time without giving a reason and without it affecting your clinical care.

What will happen to me if I take part?

If you decide to take part the research involves having some blood samples taken before and after standardised test meals which we will provide for you. We will ask you to eat a meal designed by our dietician the evening before you come to hospital for the study. After this meal you will then fast for at least 8 hours before you come to the hospital (although you can have plain tap water to drink). As your appointment will be at 8am the following morning we will ask you to stop having anything to eat from midnight onwards. The following morning when you come to the hospital we will put a small tube (cannula) in the back of your hand or arm. This is the same as the ones used for anaesthetics if you are having an operation. We will use this to take the blood. It will mean that you should only have to have one needle inserted during the whole day and will be removed before you go home. Alternatively, if you prefer to have each blood sample taken using the usual method of collecting blood (the same as when you have had blood taken during your pregnancy) we can do it this way too. This method needs to be repeated every time you have a blood sample collected.

The first blood sample will be taken shortly after you arrive and while you are still fasting. You will then be given breakfast which we will provide. After breakfast we will then ask you to give some more blood sample, 1 and 2 hours after you have eaten. The final samples will be taken before and after you have had lunch which we will provide. These samples will be taken at timed intervals for up to three hours after you have eaten your lunch. In total we will take 9 blood samples. This will not exceed 9 tablespoons of blood. The whole procedure will take approximately 8 hours.

If you are not pregnant we will we will ask you to participate in the study only once. If you are pregnant we may ask you to participate in the study several times (maximum three times) which we may be asking the women who develop ICP to do. This will allow us to investigate the variations in the levels of lipids, glucose and hormones at different time points during pregnancy. However, if you prefer to only take part once this will still provide us with very valuable information for our study.

On the day of the study we will also ask you to provide us with a urine sample and, if possible, a stool sample. This is because we know that bile acids are excreted in urine and stools and we can measure these and other substances that may help us to better understand the condition.

When you have your baby we would also like to be able to have some samples from the placenta and from the cord blood of your baby. These are taken after you have delivered your baby so there is no risk of harm your baby. These samples will allow us to look at how metabolites such as glucose, lipids and hormones may have an effect on the placenta and your baby. We will use these samples to investigate the role of food in the regulation of bile acids and other metabolic factors that may cause complicated pregnancy.

What are the possible disadvantages and risks of taking part?

Apart from giving the blood samples, there are no disadvantages of taking part in the study. Having the cannula inserted or the blood sample taken may involve some discomfort to you, but this will be minimal. There is no risk to your baby from any part of the study.

We will not be able to give you personally any specific results from this study. However, you should be aware that there is a possibility that the methods used in this study may produce an unexpected result that may have relevance for your health. In the unlikely event of this happening, we will discuss this with you and, if necessary, provide any support that you may require, such as arranging follow-up tests and/or treatment.

What are the benefits of taking part?

There is no intended direct clinical benefit from taking part in the study. However information from the study may give knowledge in the future about complications of pregnancy that will reduce illness and possibly death both for mothers in pregnancy and their babies.

We will also give £20 in high street gift vouchers every time you take part in a study day as recognition of your contribution to the study and to thank you for your time. We will also reimburse you for any travel expenses incurred as a result of taking part.

What if something goes wrong?

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 Chief Investigator, Professor Catherine Williamson 0207 848 6014 The normal National Health Service complaint complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Office.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. All samples will be coded for the laboratory work and, therefore, your name will not be linked to the sample. The only people who will be able to identify you are members of the research team. If information about your medical history is used in medical or scientific publications we will ensure that your name is not linked to the information. We will let your GP know that you are taking part in the study but no information you provide us with will be passed on to him/her. We sometimes send our samples to other research groups who may be outside the EU who we are collaborating with. Any of your samples that we send will not have any identifiable information about you on them, they will simply have a number.

What will happen to the results of the research study?

We plan to publish the findings of the research in a medical/scientific journal.

Who is organising and funding the research?

This research study is being organised by Professor Catherine Williamson who is funded by the Wellcome Trust. It is also supported through internal funding.

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 your interests. This study has been reviewed and given a favourable opinion by NRES Committee London – Queen Square.

Study team contact details

If you require any further information about this study, or you have any questions you can contact the following research team members: INSERT NAME

Thank you for taking part in this study.