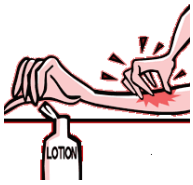
Imperial College London

INTRAHEPATIC CHOLESTASIS OF PREGNANCY RESEARCH 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information. The study team contact details are at the end of this information sheet.

Quick Summary of the Research

- **Around 5,500 women in the UK develop intrahepatic cholestasis of pregnancy (ICP) every year**
- **It's not life threatening to the woman (although the itching can sometimes be extremely distressing) but there can be problems for the baby such as fetal distress, spontaneous premature labour and, in severe cases, stillbirth**
- **Researchers are investigating several factors of ICP:**
  1. **Genetics – to understand why it is seen in families**
  2. **Hormones – ICP only occurs in pregnancy and usually (but not always) when the pregnancy hormones are at their highest**
  3. **Metabolites – are substances that can generally be measured in the blood and which are the end result of all the chemical changes that take place in the body on a day to day basis. Metabolites such as bile acids are thought to be the cause of problems for the baby in OC but it is possible that the condition causes high levels of other metabolites, e.g. glucose and cholesterol that may also be important**
  4. **Environment – the severity of ICP can be affected by diet, taking antibiotics or viral infections**
- **Women are being asked to donate samples such as blood and urine at various points during and after their pregnancy to help scientists better understand the condition**
- **Some women who have to have surgical procedures such as CVS (chorionic villus sampling) may be asked to donate any spare tissue left over from the procedure**
- **This in turn may help doctors to manage ICP pregnancies more effectively which could ultimately help to protect the unborn baby**

If you are currently pregnant, we realise that we are asking you to consider taking part in research at a very special time of your life and we do not wish to intrude. However, we need to recruit enough women to the study in order to make progress in our understanding of ICP so we hope that you don't mind that you have been approached in this way. If you think you may wish to be involved please read on (this still doesn't commit you to anything) otherwise we thank you for agreeing to read this far and wish you all the best in your pregnancy.

If you are not currently pregnant but are interested in taking part please read on otherwise we thank you for taking the time to read this far.

The purpose of the study

We are interested in studying diseases of pregnancy (ICP in particular) that can affect the health of the mother and baby. In particular we are trying to understand what genetic and metabolic factors (the chemical changes that take place in the body) can make the mother unwell during pregnancy, and which of these can also make the baby unwell when in the womb. We have been taking samples from women that include blood, urine, faeces and placenta to study these different factors.

We hope that by learning more doctors will eventually be able to offer women better treatment that helps to improve their symptoms (such as reducing the itching) and ultimately protect their unborn babies.

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. 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. To date we have recruited just under 4000 participants and we aim to recruit a further 550 samples to enable us to complete our work.

Do I have to take part?

It is completely up to you whether or not to take part. If you choose not to it will not affect your medical care either during or after pregnancy. If you do decide to participate you will be given this information sheet to keep and be asked to sign a consent form (and one on behalf of your baby if you're pregnant). **On these forms you can indicate which samples and how many of each you are willing to let us have.**

There are generally no restrictions on behaviour, eating, or lifestyle specific to any of the tests.

What do I have to do? – During Pregnancy

There are several ways in which you can take part in the research which may include all or some of the following:

- Completing questionnaires regarding your medical and family history
- Completing a questionnaire about sleep and eating patterns as this will provide information that could help scientists discover if the times women eat and sleep make them more susceptible to developing ICP
- Donating a sample of blood so that we can look at your DNA (genetic information)
- Donating some blood samples that will allow us to compare your hormones and metabolites (such as progesterone and bile acids) with women who have ICP
- Donating some urine to allow us to look at hormones and metabolites
- Donating stool samples for us to look at metabolites
- Donating some tissue if you are having a procedure called CVS (chorionic villus sampling)
- Letting us have a sample of the fluid that surrounds your baby (called amniotic fluid) if you are having a procedure called amniocentesis. This procedure involves drawing some of the fluid off through a needle inserted into the womb and is generally only done if your doctors thinks it is important for the safety of your baby. This rarely happens in women who are having uncomplicated pregnancies.
- Allowing us to share your samples with other researchers or organisations to help them develop better ways to test bile acids in ICP

The DNA sample is generally a 'one off' blood sample and may help us to understand how disorders such as ICP are passed down through families. We need your DNA to make sure that any genetic variants we find in ICP that we think are important cannot be found in women who don't have the condition. If you are needle phobic we can take a saliva or buccal sample. Both are very easy to provide, one involves you spitting into a pot and the other involves using a soft brush to scrape some cells from your cheek.

The other samples can also be donated just once or, if you are willing, can be given to us several times during your pregnancy to form what we call 'serial samples'. Collecting serial samples will help to give us a 'picture' of an ICP pregnancy and we hope that by obtaining a record of the pregnancy in this way we may be able to pinpoint where in pregnancies disorders such as ICP cause problems. We need comparison serial samples from women without ICP. We will ask you to consider allowing us to have at least three serial samples but just one sample will be very valuable to us. The amount of blood we will take is small – approximately 10 ml of blood which is less than two teaspoons.

At the same time we take blood from you we will ask you to provide a urine sample in the standard urine containers that you are given by the midwives. We would also appreciate at least one stool sample from you (three samples in total during the pregnancy if possible). We will discuss how to collect this when we recruit you to the study.

Occasionally we may ask you to fast for these comparison samples as they can give a different result compared to non-fasting samples.

Some women (with or without a history of ICP) may have procedures such as CVS (chorionic villus sampling) in their pregnancy and we may ask them if we are able to have any spare tissue that is left. This is because research as shown that bile acids may affect the placenta and scientists want to have a better understanding of the placenta in early pregnancy.

You can tell us at any stage in your pregnancy that you wish to stop donating samples and it will not affect your medical care.

When you have your baby we would also like you to consider donating the following comparison samples for after he or she has been born when the cord has been cut and the placenta delivered. Taking these samples cannot harm you or your baby

- Cord blood samples for DNA and metabolites
- A small piece of umbilical cord if required (for example if we are unable to obtain cord blood)
- Placenta to look at how your placenta compares to one from someone who has had ICP
- The very thin membrane that surrounds the placenta called the amnion
- Urine for metabolites (we can spin the nappy to obtain some urine)
- Stools samples (also taken from the nappy)

You can donate all or some of these samples and it may be that we will only need some samples such as cord blood or placenta. We will discuss this with you when you are due to have your baby. You can either consent to this in advance or wait until nearer the time of delivery if you are happy for us to have some or all of these samples – it is up to you.

What do I have to do? – After Pregnancy

We may ask women who have had ICP to let us have some samples when they are not pregnant. Samples such as blood, urine or stools taken at this stage may help scientists to learn more about what happens to the metabolites and hormones after pregnancy or before the woman develops ICP in a subsequent pregnancy and may help researchers better understand how the condition develops. This could mean that new ways of diagnosing the condition early might be identified and treatments developed to prevent ICP occurring. We will also need comparison samples from women who have not had ICP but you are not under any obligation to have to do this.

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 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 your results may produce an unexpected result that may need further investigation or monitoring (for example we may check your lipids (fats) which may be high and require further investigation from your GP). If this happens we will discuss this with you and, if necessary, provide any support that you may require, such as advising you to contact your GP, if appropriate, or 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 ICP that could help doctors treat the condition more effectively and perhaps even prevent the risk of stillbirth from the condition.

What if something goes wrong?

Imperial College London is sponsor for this study and holds insurance policies which apply to it. 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 Chief Investigator, Professor Catherine Williamson: 0208 383 5281. 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 Research Governance and Integrity Team.

How will we use information about you?

Research Study Title: ICP Research Study

Imperial College London is the sponsor for this study and will act as the Data Controller. This means that we are responsible for looking after your information and using it appropriately. 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.

The study is expected to finish in January 2026

For more information / confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information from you and sometimes from you and from your medical records for this research project. This information will include your:

- Initials
- NHS number
- Name/ contact details
- Date of birth

People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact) details is accurate**.** 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.

Some of your information will be sent to other researchers conducting research into ICP. They must follow our rules about keeping your information safe. 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.

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. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

> Imperial College London - "performance of a task carried out in the public interest"); 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

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), (both organisations / Imperial College London) rely/relies on "scientific or historical research purposes or statistical purposes

International transfers

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. 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 UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London 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.

Commercialisation

Samples / data (delete as required) from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

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 because some research using your data may have already taken place and this cannot be undone.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us and we will stop. This will not affect any healthcare or support you may be receiving separately

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 this could affect the wider study or the accuracy of data collected.

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.

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 jenny.chambers@imperial.ac.uk
- or by ringing us on: 0208 383 5285

Complaint

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to jenny.chambers@imperial.ac.uk or by ringing us on 0208 383 5285

Following our response, if you are not satisfied 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 remain unsatisfied 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)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the West London Research Ethics Committee: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/london-west-london-gtac/

Contact for further information

Please contact (insert local contact details) at the following address (insert local contact details)

What will happen to the results of the research study

We plan to publish the findings of the research in a medical/scientific journal. It is possible that we may identify something that has implications for you, for example, a genetic change that may cause you to be at risk of another liver disease, such as gallstones or which means there are certain drugs you should avoid because they may harm your liver. In this instance we will be able to contact you to let you know about this. If you do not wish us to be in contact you will be able to mark this on the consent form.

Who is organising and funding the research?

This research study is being organised by Professor Catherine Williamson who has been funded by The Wellcome Trust, Action Medical Research, Wellbeing for Women, Genesis Research Trust, The Medical Research Council, Tommy's, ICP Support,

Thank you for taking the time to read this information sheet and, if you choose to, taking part in this study!