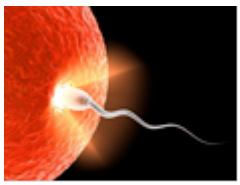
Guy's and St Thomas' NHS
NHS Foundation Trust

Paternally Inherited Phenotypes in Cholestasis Study (PIP-C)



Participant Information Sheet

Our study title – Paternally Inherited Phenotypes - means looking for physical and biochemical characteristics that can be seen and measured in an individual, this includes characteristics like height and weight or even sugar and fat levels in the blood.

You are being invited to take part in a medical research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully. You may find it helpful to discuss it with someone else, for example a family member or friend. If there is anything that is not clear or if you would like more information, please contact us – our details are given at the end of the 'Quick Summary'.

Quick Summary

- **There is increasing evidence that a father's health at the time of conception of his child can influence the child's health in the future.**
- **It is likely that this is due to subtle changes in the structure and function of the sperm.**
- **We are interested in studying these changes, and in particular how cholestatic liver diseases such as Primary Biliary Cholangitis and Primary Sclerosing Cholangitis may influence the structure and function of the sperm.**
- **You are being asked to consider taking part because you have a cholestatic liver disease.**
- **The study will involve completing a questionnaire about your health and donating a semen and blood sample to us.**

Study Team contact details

If you require any further information about this study or have any questions you can contact:

Principal investigator: Professor Catherine Williamson, E-mail address: catherine.williamson@kcl.ac.uk
Trial Coordinator or research team member: Ms Jenny Chambers, E-mail address: jenny.chambers@imperial.ac.uk; Ms Vanessa Pataia, E-mail address: vanessa.formigo_pataia@kcl.ac.uk

The purpose of the study

For some years we have known that the health of fathers at the time their baby is conceived has an influence on the health of their child in the future. Many studies looking at this effect have investigated fathers with obesity and other metabolic disorders. These disorders are associated with an increased risk of obesity and diabetes in the children of these men. More recently, studies have been undertaken to establish the mechanism by which this risk is inherited by the children. Studies of sperm have identified that changes in the structure and function of the sperm play a role.

Our group is interested in cholestatic liver diseases. This is a group of liver disorders that are associated with elevated levels of bile acids in the blood. We have recently established that children born to women who have cholestasis during pregnancy are at an increased risk of obesity later in life. We would now like to investigate whether there is a similar effect on the health of children if their father has cholestasis.

Our study will aim to look at structure and function of sperm from men with cholestasis and compare this to the structure and function of sperm from healthy men. You are being invited to participate in the study as a man with cholestasis.

Why have I been chosen?

We would like to invite you to join our study as you have a cholestatic liver disease. We plan to recruit at least 40 men with cholestasis to the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. You will be free to withdraw from the study at any time and you do not have to give a reason for your decision.

What will happen to me if I take part?

If you decide to take part in the study, we would like to ask you to do the following:

Once you have consented to take part:

- We will ask you to attend the Assisted Conception Unit at Guy's Hospital or the Birmingham Women's Fertility Centre, who are two participating centres in this study.
- On the day of your attendance you will be given a health questionnaire and a semen collection pot.
  We would ask that you:
  - Complete the health questionnaire.
  - Use the semen collection pot provided to collect a semen sample. We would ask that you abstain from sexual activity for a minimum of 2 days before attending the unit to provide the semen sample.
  - Allow a health professional to collect a small blood sample from you so we can test your liver function, sugar and fat levels in the blood. For these tests we will need two tubes of blood (approximately 10 ml or two teaspoonfuls).
  - If you would prefer, you can take the questionnaire and pot home with you so that you can collect your semen at home on the day of your next appointment to bring with you. Your questionnaire can also be completed at home and brought in on the day. Your blood sample would be taken at your appointment on the same day.

If you have consented to participate in the study, but we do not receive any questionnaire or samples from you we will contact you around 12 months after you were recruited to check if you still wish to participate in the study. If you change your mind at any point you can let us know by sending an email to the Trial Coordinator or the named member of the research team.

What are the possible disadvantages and risks of taking part?

Apart from giving a blood sample, which may cause some mild initial discomfort, there should be no risks to you in taking part in the study.

If when the blood tests are performed there is an abnormality that may affect your health, you will be contacted and appropriate follow up will be arranged for you.

As part of the procedure to process the semen sample you provide us, we will need to perform a sperm count. This may reveal information on the number of sperm present in your sample. In some cases this may have implications for a man's fertility. In the consent form we provide, you will be able to tell us whether or not you would like to be informed of any problems regarding your sperm count. In case that you would like to be informed, you will be contacted and the appropriate follow up will be arranged for you.

What are the benefits of taking part?

There is no intended direct clinical benefit to you from taking part in the study.

Information collected during this study may help doctors understand and manage better the different aspects of cholestatic liver diseases. In the future, it may also result in better medical care and monitoring for the children of men with cholestasis.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Please contact: Principal Investigator: Professor Catherine Williamson, E-mail address: catherine.williamson@kcl.ac.uk.

If you have a complaint, you should talk to the researchers who will do their best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through the Guy's and St Thomas' Patient Advisory Liaison Service (PALS) on 0207 1887188, address: PALS, KIC, Ground floor, North Wing, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. When your samples are received they will be logged and allocated a number before they are stored and only members of the research team will know who those samples belong to. This is called a 'linked anonymised' process. 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. All data that are collected as part of this study will be stored in the research team's laboratory at King's College London. Original copies of questionnaires and consent forms are stored in a locked filing cabinet in a locked room, and electronic data are stored on a study specific, password protected database. Data will be stored for a maximum of 15 years.

What will happen to the results of the research study?

We plan to publish the findings of the research in a medical/scientific journal. If you would like a copy of this publication we can send this to you so please let us know. We will also send results of your samples' analysis to your GP if you have given your consent for us to do this. If you would like to further discuss any of your samples' results you will be able to book an appointment to see Professor Catherine Williamson, the study's principal investigator.

What will happen to my samples should I decide to withdraw from the study?

Should you wish to withdraw from the study we will need you to let us know, in writing. We will then destroy all your samples and data and write to you to let you know that we have done this.

Who is organising the research?

This research study is being organised by Professor Catherine Williamson, King's College London.

I'd like to take part - what do I have to do now?

We will ask you to sign a consent form to say that you understand what the study involves and that you agree to participate. You will be given a copy of the information sheet and a signed consent form to keep.

This study will form part of the PhD research thesis of Miss Vanessa Formigo Pataia.