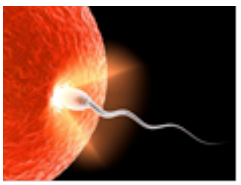
Guy's and St Thomas' NHS
NHS Foundation Trust

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 how a cholestatic liver disease in fathers at the time they conceive a child may influence the health of their child later in life.**
- **You are being asked to consider taking part because you are a father who developed cholestatic disease after the conception of your child, and your child is now aged 16 – 25 years old.**
- **The information you provide will allow us to make proper comparisons to fathers who already had a cholestatic liver condition at the time that their child was conceived.**
- **The study will involve completing a questionnaire about your health and your partner's health at the time of conception and while pregnant with your child.**
- **We will also ask you for authorisation to contact your child regarding the study, to ask them if they would like to take part.**
- **If your child is interested in participating in the study, we will ask them to complete a questionnaire about their health. We will also ask for a small blood sample (approximately 10 mls or two teaspoonfuls) that will measure substances that include, bile acids, fats and sugars (associated with cholestatic disease, obesity and diabetes and which we explain more about below) to see if there are any differences between these results and those of children whose fathers did have cholestatic disease at the time they conceived their children.**

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 and it is now known that these disorders are associated with an increased risk of obesity and diabetes in the children of these men. More recently, researchers have been trying to establish how this risk is inherited by the children and 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 look at basic health characteristics, such as waist measurement, in fathers who had cholestatic liver disease at the time of conception of their child, and also the same characteristics in their children during late adolescence/early adulthood. We will assess these characteristics by comparing them to fathers who developed cholestasis only after their child was conceived. You are being invited to participate in the study as a father who developed cholestasis after your child was conceived, and your child is now between 16 – 25 years of age.

Why have I been chosen?

We would like to invite you to participate in the study as a father who developed cholestasis only after your child was conceived. We also hope to recruit your child who is now between 16 and 25 years old. For our study, we aim to recruit 30 pairs of fathers and their children from this particular group.

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, you do not have to give a reason for your decision and it will not affect any medical care you are currently having or will have in the future.

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 send you a pack containing a questionnaire about your medical history and any complications you and/or your partner had during the conception and pregnancy of your child.
- In the questionnaire we will also ask you for the contact details of your child who was conceived while you had cholestasis and is now aged 16 – 25 years old.
- We will ask you to post the questionnaire back to us using the instructions enclosed in the pack. Returning the pack to us will be free of any costs for you.
- If your child would like to take part in this study we will ask them to complete a questionnaire providing details about their past and current health. We will also ask them for a small blood sample so that we can

measure their bile acid, fat and sugar levels in the blood. In total we would like to take two tubes of blood (approximately 10 mls or two teaspoonfuls).

We will use this information to study whether cholestasis can influence the health of children from men who already had cholestasis at the time they conceived a child.

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. This is because samples may get lost or you may just not have had a chance to send us anything but still wish to participate. 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?

There should be no direct disadvantages or risks to you in taking part in the study.

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 better the factors that influence disease risk in children from fathers with cholestatic liver disease, and in the future may result in better medical monitoring and care for these children.

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.

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.