

# **The use of comparative genomic hybridisation in the investigation of abnormal antenatal ultrasound**

## **Participant information sheet      Version 3.0**

You are being invited to take part in a research study. Before you decide 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. Talk to others about the study if you wish.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### **Part 1**

#### **What is the purpose of the study?**

During pregnancy invasive tests such as chorionic villus biopsy (CVS) or amniocentesis are often done to determine if babies have conditions such as Down's syndrome. These conditions are caused by the baby having abnormal chromosomes, for example in Down's syndrome the baby has an extra chromosome 21. The laboratory checks the sample for the presence or absence of the extra chromosome. Comparative genomic hybridisation (CGH) is a different lab test that allows us to closely look at the chromosomes. We are studying it's application in pregnancy, to find out if it could be a useful test when a baby has abnormalities on a scan.

#### **Why have I been chosen?**

You have been asked to participate because you are at increased risk of having a baby with a chromosomal problem. You have decided to have a test, either a chorionic villus biopsy or amniocentesis, to clarify this.

#### **What will happen to me if I decide to take part?**

We will ask for an extra blood test from you and your partner. We may need to examine your chromosomes and compare the baby's test results with yours, if necessary. The chorionic villus sample or amniocentesis will take place in the usual way. The normal tests will be performed on the sample. When these are complete a small amount of the remaining tissue will be transferred to the research team. The samples will be anonymised so that the research team do not have any personal details on you.

#### **Will I receive any results?**

No. The tests take too long to be able to use any results in the timescale of your pregnancy, and all of the information is anonymous. This means we will not be able to link you to the test results. We hope that if this test is shown to be useful then it will be available for patients like you in the future, but it will not be possible to get any information for this pregnancy or find out any results for any future pregnancies.

**What do I have to do?**

A researcher will discuss the study with you and answer any questions you may have. When you are satisfied you have all the information you require and decide to take part, you will be asked to sign a consent form.

**What information will we hold?**

We will hold information that is routinely collected as part of your standard care. We will also hold information that we gain from the biological samples we have taken but this will be anonymous.

**Are there any possible disadvantages to taking part in the study?**

We do not think that taking part in this study will harm you in any way, the only extra procedure is a blood sample from you and your partner. If at any point you would like to discuss the study and your involvement in it, you will be able to speak to a study researcher. Contact details are provided at the end of this sheet.

**Are there any possible advantages of taking part in the study?**

There are no immediate short term advantages, however we hope that CGH will give us more information about why some babies with apparently normal chromosomes have abnormal screening tests and scans. By increasing understanding in this way we may in the long term be able to offer better help to pregnant women.

**Do I have to take part?**

No. 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 be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

**This completes Part 1 of the Information Sheet.**

**If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.**

## **Part 2**

### **What if new information becomes available?**

We hope that this study will uncover new causes for abnormal screening tests. However the samples you provide will be anonymised so no information directly related to you will be generated. The research process is a long one and at present we would not be able to complete the tests during the course of your pregnancy.

### **What if there is a problem?**

#### **Complaints:**

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation the united Leeds Teaching Hospitals Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **How do we ensure confidentiality?**

All information recorded on paper and any biological samples stored will be kept under conditions of strict confidentiality as required by law in the data protection and human tissue acts. The samples you provide will be anonymised. A study number, which can only be linked to you by the research team, will be the identifier of the information, this is necessary so that we can put together your information throughout the study. The results from any information or biological samples that we collect will only be used for research purposes and will not be available to anyone else.

### **Will my General Practitioner/Family doctor know I am part of this study?**

No, we do not plan to contact your GP. No clinically relevant information will be generated by the study and the only extra procedure is a blood sample from your partner.

### **What will happen to any samples I give?**

The sample will be bar coded, it will not be possible to identify it as coming from you. It will be sent to our lab and DNA will be extracted. At the end of the study all the samples will be destroyed.

### **Will any genetic tests be done?**

Comparative genomic hybridisation tests will be performed on tissue remaining at the end of the routine lab procedures. The samples are fully anonymised, results for individuals are not meaningful at this stage but the research may assist in the development of future testing programmes which may then be available through the NHS.

### **Who is organising and funding the research?**

The study is organised by the University of Leeds, and funded by Leeds Teaching Hospitals Trust and the charity Wellbeing of Women.

**CONTACTS**

Dr Kelly Cohen, Research Fellow or Dr Eamonn Sheridan, Consultant  
Dept of Clinical Genetics  
St James's University Hospital  
Beckett St  
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**COMPLAINTS**

Please contact the research team above in the first instance. Assistance is also available from the Hospital Complaints Line on (0113) 206 6261, or write to the Chief Executive, St James's University Hospital, Beckett St, Leeds LS9 7TF