Participant Information Sheet

Participation in the Research Study: iFIND (Intelligent Fetal Imaging and Diagnosis)

Data from your 18^{+0} to 22^{+6} weeks screening ultrasound scan

You will be given a copy of this information sheet.

Invitation to take part

We are inviting you to take part in a research study, which will use data collected during the routine ultrasound scan to image your baby. 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 and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

We would like to improve the accuracy of the 18^{+0} to 22^{+6} week ultrasound scan to make sure we pick up as many of the abnormalities that could be detected. In this study we would like to develop an ultrasound system that will improve screening for fetal abnormalities. We are proposing new technologies to automatically detect any abnormalities a baby could have. This would improve the rate of detection of abnormalities to ensure that in the future more babies with potential problems are picked up and treated as soon as possible. We will use data from normal ultrasound scans to 'teach' our computer programme what a normal baby looks like. All babies are different so we would like to save the data from as many scans as possible so that the computer can learn the range of different sizes and shapes a baby can be.

What will happen to me if I take part?

If you are happy to take part we will save the ultrasound data from your scan to use for research to help us improve ultrasound scanning in the future. If you agree to this, the scan itself will be performed exactly as usual but instead of only a selection of snapshots of the baby being recorded, as is usually the case, the data from the whole ultrasound recording from your scan will be saved and retained for this research study. With your permission we would also like to collect information on your delivery and baby's outcome. Any personal information which could connect the data to you or your baby (name, date of birth etc) will be removed and replaced by a Study Identification number. Only the ultrasound data that would normally be saved from your scan will be available to you. To help us develop our research we will also use the information collected routinely in your maternal notes and on hospital databases.

What are the possible benefits of taking part?

The ultrasound scan at 20 weeks is done to see how your baby is developing and check that he/she is healthy. If you are happy to take part in the study and have the data from your scan saved there will be no direct benefits to you, but this research may improve ultrasound scanning in the future and provide better diagnosis of fetal abnormalities.

What are the possible risks of taking part?

None.

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 see the contacts sections for details.

If you have a complaint, you should talk to your doctor 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, c/o KIC, Ground floor, North Wing, St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH.

The trial is co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation Trust. The sponsors will at all times maintain adequate insurance in relation to the study independently. King's College London, through its own professional indemnity (Clinical Trials) and no fault indemnity cover, in respect of any claims arising as a result of clinical negligence by its employees, brought by or on behalf of a study patient.

Will my taking part in this study be kept confidential?

The information obtained from your study is covered by the Data Protection Act. The computerised information is protected by a software and hardware barrier and the records are handled in the same way as hospital records. Only responsible individuals from Guys and St Thomas' NHS trust and Kings College London, or from regulatory authorities will have access to your clinical records. This information would be given to us by your obstetrician and would be handled confidentially. We will remove any personal information which could connect the data to you from any imaging data that is shared with colleagues in collaborating units.

Who is organising and funding the research?

The research is organised by and Kings College London and Guys and St Thomas' NHS Foundation Trust and is funded by the charity the Wellcome Trust and the Engineering and Physical Sciences Research Council.

Who has reviewed the study?

The study has been reviewed by the London – London Bridge REC ref. 14/LO/1805.

Contacts for Further Information

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