

Participant Information Sheet

You will be given a copy of this information sheet.

Study Title: iFIND (Intelligent Fetal Imaging and Diagnosis)- Further Ultrasound and MR Imaging

Invitation to take part

We are inviting you to take part in a research study, which will use data collected during a further 2D and 3D ultrasound scan and an MRI 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.

Why are we carrying out this study?

In a small minority of cases it may be important to be able to spot any potential problems with the fetus (baby) before he/she is born. Making a diagnosis prenatally (before a baby is born) allows the expectant parents to make informed choices about whether or not to continue with the pregnancy. It can also improve a baby's prospects by allowing a treatment plan to be produced from the moment the baby is born. We would like to improve ultrasound scanning so that in the future all babies have the best outcome possible.

Ultrasound passes sound waves into the body to create pictures from their reflections. It is commonly used to see if babies in the womb are healthy. Although every pregnant woman in the country has a scan at around 20 weeks, not all of the babies who have problems are picked up on these ultrasound scans.

Magnetic resonance imaging (MRI) is a method of obtaining pictures of the inside of the body. While ultrasound is excellent for showing the anatomy (body) of the normal fetus, magnetic resonance (MR) is usually better for detecting and assessing both normal structures and abnormalities in more detail. The MR technique uses a large magnet and radio waves. It does not involve the use of either X-rays or radiation. It is not believed to have any hazard associated with it, although care is needed to keep metallic objects away from the magnet.

What is the purpose of this study?

In this study we would like to develop a new computer-guided ultrasound system that will improve screening for fetal abnormalities. We are proposing new technologies that allow scanning to be carried out not just with one probe (the device which takes the ultrasound picture), but up to four probes that can be used at the same time, and which move automatically to the right place to get the best pictures. This will mean we get a detailed picture of the whole baby which can then be analysed in an automatic way to ensure we do not miss babies with potential problems.

Why have I been chosen?

We seek permission for these studies from:

1. Women with a pregnancy at 18 weeks or later at the time of scan
2. Women that are 18 years of age and over
3. Women where antenatal ultrasound is either normal or has shown a problem with the fetus.
4. Women who can read this information sheet and understand the purpose of the study and what it would involve.

Do I have to take part?

It is up to you to decide whether or not to take part. Please read this information sheet to help you to decide. A member of our research team will phone you in a few days' time to ask if you would like to take part and give you any more information you may need, so if you are interested please make sure the person who gave you this sheet has your telephone number. We have a limited number of scan slots per week so if you are keen to take part then please email us on IFIND@gstt.nhs.uk. We will then contact you, either by phone or email, to answer any questions and arrange your scans. If you do decide to take part you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

If you choose to take part we would like to take some additional ultrasound images of your baby and use the data to teach our new imaging system the best way to capture high quality images. We would also like to collect as many images as we can to build a database of fetal anatomy which computer programmes can use to compare with new ultrasound images. In this way we hope to be able to automatically detect different fetal organs and diagnose whether or not they are developing normally. To help us develop our research we will also use the information collected routinely in your maternal notes and on hospital databases.

There are two sections of this study for which we will need your help:

1. Having an additional ultrasound scan

We would like you to have an additional ultrasound scan lasting around 45 to 60 minutes (or around 90 to 120 minutes if you are carrying twins), to be performed by a trained fetal sonographer with the aim of acquiring new images. These will include regular 2D images, as well as 3D images and images that will measure the blood flow in different parts of your baby's body, such as their umbilical cord and heart. These images are used to help to develop our proposed automated ultrasound system. The standard ultrasound probe will be fitted with a holder that measures the position and the pressure exerted on the abdomen during the scan. We may also use our research equipment that lets us use more than one ultrasound probe at a time to view your baby from different angles to see if that gives us a better view of the baby. This data will be used to teach our new system how to position ultrasound probes to get the best quality scan images and what the safe pressure limits are that the automated systems can use without causing discomfort. We may also ask you to place some removable pads on yourself so we can record if we need you to lie in a certain way (e.g. on your side) during the scan. We may also ask if we can save some information about you, such as how many weeks pregnant you are; your height and weight; and the width and shape of your abdomen. We will use this information to see if these factors affect the positioning of the probe and the pressure which is used during your scan. If you are happy for us to do so we may film how the probe needs to be positioned on your abdomen to get the best images.

2. Having an MRI scan

A fetal MRI scan will also be performed. The actual time scanning the fetus will be about 60 minutes but we may need additional time to get you comfortably positioned on the table and prepare you for the scanning. This will involve you:

- getting changed into metal-free, comfortable clothes
- having your temperature taken before and after the scan
- being asked to lie on a bed that is moved slowly into the magnet
- having an oxygen sensor on your finger/ toe to monitor how you're doing during the scan

To make sure you stay comfortable during the scan we can offer you a break of up to 15 minutes half way through the scan. The scanner is quite noisy so we will give you some headphones and you can listen to some music during the scan if you wish. The noise will not harm your baby and is not as loud as going to a concert. Your partner or a friend or relative may accompany you into the scanning room once they have had a safety check. You will be given an emergency button to press to stop the examination at any time. You can go online and watch a short video explaining the MRI procedure in more detail and what you can expect when you come for your scan: <http://vimeo.com/37368763>. At the end of the scan you will be given a copy of the MRI scan pictures, including a short video (or cine) of your baby, to take away with you.

This ultrasound and MRI data will be used to build a map or atlas of the fetus and the detailed images used to help the computer recognise different organs and anatomy. Any personal information (name, date of birth, etc.) which could connect the ultrasound scan data to you will be removed. It will be replaced by a Study Identification number. With your permission we would also like to collect information on your delivery and your baby's outcome.

What do I have to do?

You will have to come to the hospital for these research scans, in addition to those in your routine pregnancy care. Most women taking part in the study will have their research ultrasound and MRI scan on the same day. If you prefer, it may be possible for you to have the research ultrasound scan and the MRI scan a few days apart from each other. For your scans we will ask you to lie as still as possible. For the ultrasound scan you will have some jelly placed on your abdomen to help the probe get the best images. For the MRI scan you will have to change into metal-free clothes and lie on a bed within a magnetic scanner while the machine produces images. You will have an emergency button to hold which you can press at any time if you would like to stop the scan.

What is the procedure that is being tested?

We are using procedures (ultrasound and MRI imaging) that are already in routine use in the hospital. We will:

- Collect more detailed ultrasound and MRI images to create fetal anatomy atlases to help develop new more automated ultrasound scanning methods
- Develop a computer guided ultrasound system where multiple probes automatically focus on the fetus

This will allow screening of fetal abnormalities in an automated and uniform fashion. We hope that this will eventually lead to a better service for pregnant women in the future and enable more fetal abnormalities to be diagnosed earlier so that appropriate action can be taken to help treat it.

What are the side effects of taking part?

The ultrasound and MRI scans themselves are not believed to have any side effects for you or your baby. The MRI scan will take place in an enclosed machine which has some inconveniences which we will try to minimise:

- People who suffer from claustrophobia and cannot travel in a lift as a result may find the scanner unacceptable, if this is the case you will not have to take part in the scan.
- Occasionally we find that the magnet is not wide enough to take women who are large e.g. twin pregnancy.
- The machine is noisy when it is acquiring images and that is why we give you some headphones whilst you are being scanned. The noise is reduced when going through your body to the baby so is 30 decibels lower for the baby than it is for you.
- Heat is produced during the MRI scan, so we will have a fan on in the scanner during the scan and will monitor your temperature to make sure that you and your baby stay comfortable.
- You will need to make an additional visit to the hospital for the comprehensive ultrasound scan and MRI scan if you are happy to have them. We will try to book these on the same day, or if you prefer them separately, within a few days of each other. In order to minimise any inconvenience this may have we can help you with the cost of transport to the hospital. This will be for the additional research scans and not your routine ultrasound scans.

What are the possible risks of taking part?

The fetal ultrasound has no perceived risks. We have thoroughly investigated all known potential risks to your baby and to the best of our knowledge and that of the medical community there are no additional risks to your baby or long-term effects of having the MRI scan. In addition, the MRI scan is not believed to have hazards associated with it when operated within National Radiological Protection Board Guidelines (which we do).

What are the possible benefits of taking part?

If you take part in the study you will be given a copy of the MRI scan of your baby, including a short video (cine) of your baby, and may (depending on your baby's position) also be given a 3D ultrasound picture of your baby. In the future we hope that the information gained from the study will lead to better antenatal diagnosis of fetal abnormalities and be used in all antenatal clinics nationally.

What if new information becomes available?

The ultrasound and MRI scans may just confirm the findings (if any) on the standard anomaly scan but there is a possibility that the additional scan might show additional information that was not seen previously. If there is any additional information, the findings will be discussed with you and with your obstetrician. This will allow your obstetrician to advise you on the management of your pregnancy with all the available information.

What happens when the research study stops?

This research study will continue for 6 years and we hope to have interesting results to publish regularly both on our website and in research journals. At the end of the study we hope that we will have reached our aim of developing a system for substantially improving the diagnostic accuracy of scans carried out by less expert sonographers.

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: iFIND@gstt.nhs.uk or 0207 188 3052.

If you have a complaint, you should talk to your research 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. We also seek permission to include clinical details about your pregnancy in the study, for instance your gestation and ultrasound details of your baby. 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.

What will happen to the results of the research study?

The results are usually published in the medical literature. No patients' names will be included. We also hope that the results of this study will help to improve ultrasound technologies in the future for diagnosing fetal abnormalities.

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/1806.

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