

What if there is a problem?

If you wish to raise a complaint on how any research organisation has handled your personal data, you can contact the relevant Data Protection Officer who will investigate the matter. If you are not satisfied with their response or believe they are processing your personal data in a way that is not lawful you can complain to the [Information Commissioner's Office \(ICO\)](#).

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available to you.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Professor Anna David who is the Chief Investigator for the research and is based at UCL Institute for Women's Health (see full address on previous page). The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

If you have a concern about any aspect of this study, you should ask to speak to a member of the study team who will do their best to answer your questions. If you remain unhappy or wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital Patient Advice and Liaison Service on 020 34567898 ext 73018.

"NHS Indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm."

Thank you for your help with this research



wellcometrust

EPSRC
Pioneering research
and skills

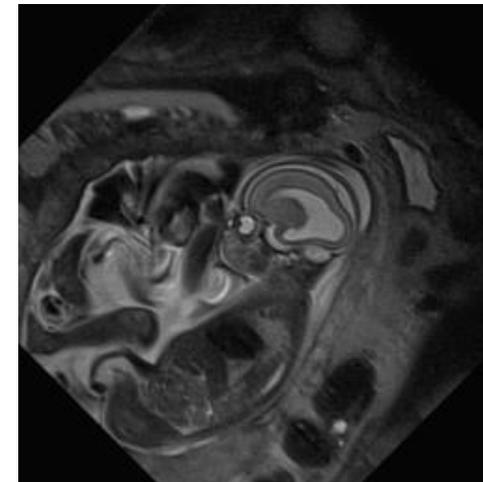
Fetal MRI to improve prenatal diagnosis and therapy

Parent information leaflet

Version 7, 3rd March 2019

Please read this leaflet carefully – it explains the research study we are doing and asks for your help. Please ask the Doctor or Midwife who explained the study to you if you have any questions

Taking part is your choice and your decision about joining the study will not change the care you get in any way



Fetal MRI to improve prenatal diagnosis and therapy

You may be aware that ultrasound is the technique doctors most often use to assess babies in the womb. The NHS national fetal anomaly-screening programme uses ultrasound scans to look for structural abnormalities in babies between 18 and 21 weeks. However ultrasound has limitations. It can be difficult to look at some structures when the baby is in an awkward position, or if there is not much fluid around the baby. Ultrasound is not so good at looking at some soft tissue structures, such as the lungs, liver, brain and placenta.

For these reasons there has been increasing interest in using other imaging methods to examine babies and their placenta in the womb. In general it is preferable to avoid ionising radiation (eg X-rays) during pregnancy, as there is a small risk of causing problems for the baby. So we only use these if it is really important for the mother's health.

Magnetic Resonance Imaging (MRI) does not use ionising radiation; instead it uses magnetic fields and radio frequency pulses to obtain images. Fetal MRI has been in use for some years and is thought to be safe.

We are asking your consent as part of our research programme to take MRI images of you and your baby. We may take some extra blood samples from you when you join the study. This will all together be about 40ml (2-3 tablespoons) and we will do our best to take the samples when you need to have other blood tests done as a part of your normal treatment. If you have your baby by caesarean section we may take a small sample (0.5cm x 0.5cm from where the placenta has been attached inside of the womb). After your baby is born the placenta and cord are usually disposed of. We may take samples of blood from the umbilical cord, and some samples of the placenta.

We believe this research may help other pregnant women, their partners and their babies in the future.

What is the GIFT-Surg project?

GIFT-Surg stands for Guided Instrumentation for Fetal Therapy and Surgery. It is a seven-year project funded by the Wellcome Trust and Engineering and Physical Science Research Council. In collaboration with Katholieke University of Leuven, Great Ormond Street Hospital and University College Hospital (UCH) we aim to develop low-risk techniques for diagnosis, treatment and therapy of a range of dangerous conditions of the baby, placenta and womb during pregnancy.

Who can give me further information?

You can contact us (see below) at any time and we will be very happy to answer any questions you may have.

You will still be attending appointments after the MRI scan and the doctor there will be aware of the study and also able to answer questions.

All the consultants on the Fetal Medicine Unit and not directly involved with the study are available to give you an independent view of the study if you would like to speak to someone else – the midwives looking after you will help you get in touch with your consultant.

Who is organising and funding the research?

The chief investigator is Professor Anna David, an obstetric consultant specialising in fetal medicine.

Professor Sebastien Ourselin, who is head of the School of Biomedical Engineering and Imaging Sciences at Kings College London, leads the technical team.

The Wellcome Trust and Engineering and Physical Science Research Council fund the study.

Who has reviewed the study?

The study was reviewed by a range of professionals during its development as we applied for funding. It has also been approved by the NRES Committee London – Hampstead (ref 15/LO/1488) and is registered with the Research and Development Department of UCLH.

Useful Contacts

Chief Investigator:

Prof Anna David
Consultant in Fetal Medicine
Director of the Institute for Women's Health.
University College London.
2nd Floor Medical School Building.
74 Huntley Street
London
WC1E 6AU.
anna.david@nhs.net
07852 220375

Clinical Co-Investigators:

Dr Nada Mufti
Clinical Fetal Medicine Fellow
nada.mufti@nhs.net

Dr Rosalind Aughwane
Specialist Registrar in Obstetrics
rosalind.aughwane@nhs.net

Dr Giles Kendall
Consultant Neonatologist
Tel: 02034478095 (Consultant's PA)
giles.kendall@uclh.nhs.uk

Are there any benefits to taking part?

This study is unlikely to be of any direct benefit to you or your baby. We hope that the knowledge from this research will benefit pregnant women and babies with medical conditions in the future.

Are there any inconveniences and risks of taking part?

Having a blood test can sometimes leave a bruise. There is no extra bruising if blood for the study is taken at the same time as blood tests for your normal medical care. The samples from the wall of the womb take about 1 minute to collect. You will not feel them and do not affect the healing of the womb.

Will any genetic tests be done?

Yes. We will only look at genes related to pregnancy, fetal growth and development and how the environment affects them (epigenetics). The results of these tests will not be available to you or your doctor as they are unlikely to affect the way we look after you in this or future pregnancies.

What will happen to any samples I give?

Samples will be tested using your study number so the results will not be available to you or your doctor. Samples will be stored securely in your hospital or transferred securely to our laboratories for specialist test. Samples will be kept for at least 5 years after the study ends. At the end of the study the samples will be transferred to a research tissue bank or will be stored by the research team pending ethical approval for use in another project for future research to give us more information relating to the pregnancy such as fetal growth restriction

What will happen to the results of the research?

The results of this research will be described to other doctors and scientists at scientific meetings and will be published in medical (peer-reviewed) journals. No individuals will be identifiable in any of this material.

What happens to the data collected in the study?

As well as the images from your scans we will access your medical records, for example to gain information such as gestation at delivery, and how you and your baby are. This will be the minimal information needed and will be fully anonymised.

All personal information collected about you during the course of the research will be kept strictly confidential and will be kept within the University College London

Hospital. The images will be anonymised and will be stored, handled and processed at the University College London. Nobody will be able to identify you from the anonymised images or data. The investigators are responsible for safety and security

of the data. The anonymised data might be shared with research institutes and companies (possibly outside the European Union) we collaborate with. Parts of the anonymised data may also be published in scientific journals and related media. With your consent we will write to your General Practitioner so they are aware of your involvement in this research.

Can you find out the results of the research?

If you wish you can opt in to receive a yearly letter summarising the progress of the GIFT-Surg project. This will not be specific to your images, and may not always be specific to MRI, as there are other areas of research, such as developing new instruments to perform fetal surgery. It will however give you an overview of the progress you have helped us to achieve.

You can also visit our website for more information and updates:

<http://www.gift-surg.ac.uk>

What is fetal surgery?

Until relatively recently it was not possible to help an unwell baby in the womb, however there is now increasing use of fetal interventions, which aim to treat the baby whilst they develop in the womb.

Twin-to-twin transfusion syndrome is a condition that occurs in 20% (1 in 5) of twin pregnancies that share a placenta (identical twins). One twin gets more than their share of blood supply, and one gets less, leading to one big and one small baby. This condition is dangerous for both babies and without intervention it carries a high chance of one or both babies dying before birth. A study has shown that surgical treatment has a better outcome for babies than any other option. The surgery involves putting a small probe with a camera, called a fetoscope, inside the womb, and burning the connecting blood vessels on the surface of the placenta with a laser, so that each baby has their own blood supply. We offer this treatment at UCH.

There is also research that shows performing an operation to close spinal defects in a condition known as Spina Bifida can improve the longterm outcome for the baby.

There are other fetal interventions that are currently being investigated, such as treatments for blockages of the urinary tract, and treatment for babies with a hole in their diaphragm. We do not know yet if these procedures will improve outcomes for the baby.

How will this research help?

Before performing fetal surgery, doctors need as much detailed information as possible, so they can understand a particular baby's anatomy, and know which is the best surgical approach to take. The GIFT-Surg project is trying to improve the quality of imaging from MRI and ultrasound.

The researchers in the project want to optimise the way the technologies make images of different parts of the baby, the placenta and the pregnant woman. They then hope to develop computer software to construct 3D images and to improve the image quality further. Finally they will design software to assist surgeons to better plan and perform fetal, placental and uterine surgery.

What does the study mean for you and your baby?

A clinical scan usually takes thirty to forty minutes. If your doctor has requested imaging we will ensure that all the required images are taken first. We would like to continue to scan, up to a maximum total time in the scanner of sixty minutes (one hour).

If you are a volunteer with a healthy pregnancy we will use the whole time for research imaging, again to a maximum of 60 minutes in the scanner.

The neonatal radiologists based at UCLH and Great Ormond Street Hospital (GOSH) will report ALL the imaging. Imaging may give additional information about your baby that could:

- Confirm previous findings
- Complicate your pregnancy care by finding something new

- Complicate your pregnancy by finding something we don't know how to interpret. As this is a developing area we may be able to tell you that something does not look normal, but we may not know if this has any long-term effects.

The results will be fed back to you through the Fetal Medicine team, so that their clinical expertise is available to answer any questions you have, and discuss what the results mean in terms of treatment and prognosis. They will be able to provide you and your partner/family with support, and will continue to look after you throughout your pregnancy.

Is Fetal MRI safe for your baby?

There are no known long-term effects to your baby from fetal MRI. Please refer to the provided UCLH Fetal MRI leaflet for a full discussion of the risk.

Is Fetal MRI safe for you?

All the regular clinical safety precautions, such as a safety questionnaire, and changing into safe clothing will be followed as normal. There is no additional risk to you because you are pregnant. The disadvantage is that you may be uncomfortable. We will try to ensure your comfort, positioning you so you do not feel faint, and supporting your body with pillows. You will be able to communicate with us throughout the scan. Participation is voluntary and you are free to withdraw at any time without giving any reason, without the medical care or legal rights of you or your baby being affected.

What images will we take?

We want to gain understanding of all the different structures associated with pregnancy. This includes looking at different areas of your baby, for example we may take pictures of the lungs, spine or abdomen. We may also take images of other structures associated with the pregnancy, such as the placenta. We may use different MR techniques to look at the structures in different ways. All techniques are as safe as routine MRI.

What will we do with these images?

All images will be reported by the clinical radiologists at UCH and the information communicated back to you via the Fetal Medicine team.

The data will be fully anonymised, so that your identity is protected. It will then be uploaded for use by researchers on the GIFT-Surg Project.

How will we use the images?

We will use the images to:

- Design computer programmes that can produce complete 3D images of different structures such as the placenta, or a baby's organs
- Develop novel software that uses imaging to help surgeons plan fetal procedures and surgery in 3D



A researcher working on anonymised fetal MRI images

More information about how we will be using your data. What are your rights?

- University College London (UCL) is the sponsor for this study based in the United Kingdom, London. We will be using information from you and/or your medical records in order to undertake this study and will act

as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 5 years after the study has finished.

- Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information

<https://www.ucl.ac.uk/joint-research-office/about/data-protection-statement>

University College London Hospital (UCLH) will keep your name, NHS number and contact details confidential and will not pass this information to UCL. UCLH will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. UCL will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

UCLH will keep identifiable information about you from this study for 5 years after the study has finished.