Information Sheet for Pregnant Women
REC Reference: 23/LO/0685

You will be given a copy of this information sheet.

Formal Study Title: Magnetic Resonance Imaging of mother and fetus in late gestation to inform and optimise BIRTH management. The MiBIRTH study.

Invitation to take part

We are inviting you to take part in a research study, which uses a technique called magnetic resonance (MR) to take images of your womb, baby and placenta.

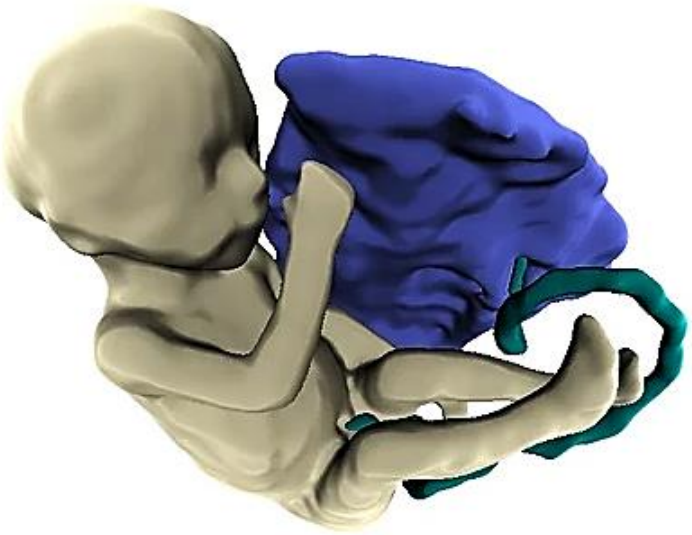
We are developing this technique further to get results that are more personalised for mother and baby. Our aim is to get more information on the best timing and mode of birth (vaginal or caesarean).

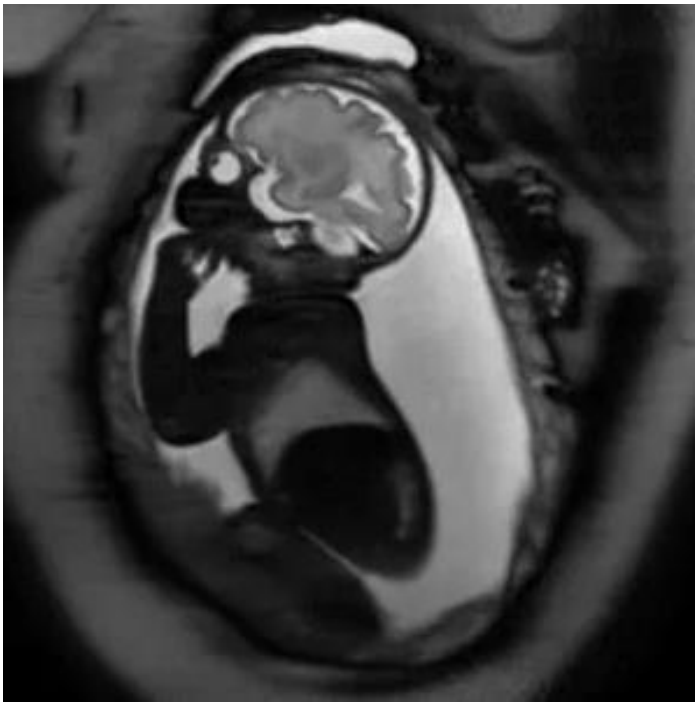
Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your partner, friends, relatives and your midwife, consultant obstetrician or GP if you wish. Ask us if there 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.

What is the purpose of this study?

Occasionally a baby may not easily pass through the mother's pelvis. Most women have a spontaneous vaginal birth (57%), with no complications for themselves or their baby, but many others may require an assisted birth, also known as an instrumental delivery (forceps or a ventouse / vacuum cup) or caesarean section (CS). It would be very helpful to predict which women may not have an uncomplicated vaginal birth so that women may make more informed choices prior to labour. Women who have a higher chance for an assisted birth or a caesarean are those who have not had a baby before (primigravida), those who have either a large or a small baby and those who have had a previous caesarean, but very often the need for intervention is completely unpredictable.

We are interested in developing a new approach based on MR imaging to improve the ability to assess both mother and baby after 36 weeks of pregnancy, to better predict how a mother may give birth. We aim to combine the MR information with data from ultrasound, clinical history, clinical examination, and a blood sample. We will use the latest ('data modelling') approaches to analyse all the data together to understand and predict whether women are more likely to have a vaginal or caesarean birth.





Magnetic resonance imaging (MRI) is a safe method to get images of the inside of your body. It can provide images of your baby, your pelvis, your placenta and also provide images of your cervix (neck of the womb). MRI is already often used in clinical practice. MRI is often used in pregnancy to assess the fetus, usually when a fetal anomaly has been detected on routine Ultrasound.

Your baby's development may influence whether you will have vaginal or caesarean birth, your pelvis may influence how your baby navigates the birth canal. Imaging the placenta, which provides oxygen and nutrients to your baby during pregnancy and labour, may provide valuable information in predicting the baby's energy levels during labour. The cervix shortens and dilates (opens) to allow your baby to pass into the birth canal. Everything matters, womb, cervix, pelvis, placenta, baby.

While ultrasound shows the anatomy of the growing baby and can provide some information on whether the placenta is working well, it does not give us much information about what will happen at the end of pregnancy or during birth. Doppler Ultrasound (DUS) is a technique to gain information about the baby's heartbeat and blood flow in the umbilical cord and mother's vessels providing blood to the womb but is not often used towards the end of pregnancy.

We are therefore asking your permission to image you up to three times prior to giving birth. Each scan will provide us with detailed information to improve the ability to predict birth outcomes. We may not have time for more than one scan in most women before they give birth, yet having even one MRI scan is still very helpful for the study. We would like to take images of your pelvis, womb, baby, cervix and placenta within the same scan. We would also like to collect some information about your baby using a portable Doppler Ultrasound device similar to that used in routine ultrasound scans. An ultrasound sensor will be attached to your tummy and connected to a small monitor attached to you.

We would also like to do an Ultrasound scan, similar to the Ultrasound scans you have had during your pregnancy. We would like to take a sample of your blood, allowing us to study important proteins (biomarkers) related to the function of your placenta. We also seek your permission to study your placenta after your birth with MR imaging and/or under the microscope (histopathology). We would like to contact you via telephone at around 10 weeks post your delivery to ask how you and your baby are doing. We will ask about your emotional wellbeing and physical health. Where possible we also seek your permission to contact you after delivery to invite you to take part in other ethically approved studies.

The study duration could be up to 4 years and we aim to recruit up to 500 women. Your involvement would be from your first scan until about 10 weeks after birth when we will ask you questions about your wellbeing.

More information on this study is available on http://www.mibirthstudy.com

Why have I been invited?

We seek permission for this study from:

1. Women who are planning to have a vaginal birth.
2. Women with uncomplicated pregnancies, OR
3. Women at higher risk for birth using forceps or ventouse or emergency caesarean birth, OR
4. Women with complicated pregnancies such as those with fetal growth restriction (when the baby does not grow well), OR
5. Women where tests have shown a possible anomaly with the fetus or placenta.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and given as much time as you need to decide. You will then be asked to sign a consent form prior to your scan and will have the opportunity to ask any further questions. 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. We will only use the data acquired up to the point of your withdrawal for the study.

What will happen to me if I take part?

As part of the study you are invited to have an MRI scan, an ultrasound scan and a blood sample. This visit will take approximately 3 hours and is booked from 36 weeks of pregnancy. We also ask your permission to collect your placenta after birth. At around 10 weeks after birth, we will invite you to complete a short online questionnaire.

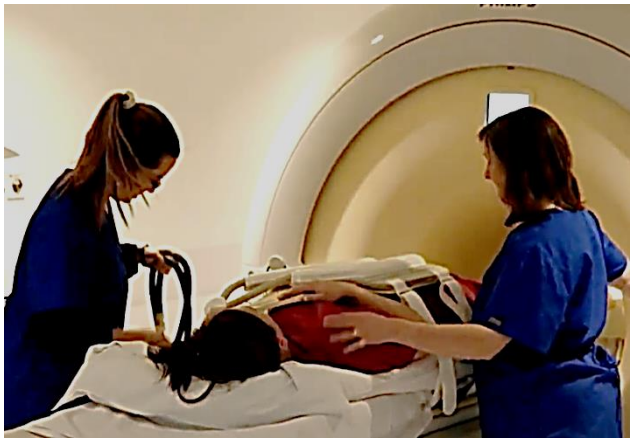
MRI scan

The MR scanner is sited in the scanner suite at St Thomas' Hospital. At your appointment you will be given metal free comfy clothes (scrubs) to change into. You will be asked to complete a metal safety check list. You will then be weighed and have your temperature taken. You will be asked to lie on a bed and made comfortable with pillows. Your blood pressure, pulse and oxygen saturations will be monitored throughout the scan. The MR scan will take approximately 60 minutes.

An ultrasound sensor will be placed on your abdomen to record your baby's heartbeat. You will then be moved slowly into the scanner. Your tummy (abdomen) will be positioned in the middle of the scanner. Your head will be level with the opening of the scanner. You will hear a variety of noises during the scan. We will give you headphones and you can listen to some music during the scan if you wish. You will be given a buzzer to press at any time if you are worried or uncomfortable during the examination. If the procedure does not suit you for any reason, it can be stopped at any time.

We will get some of the data with you in two different lying positions in the scanner, on your side and on your back. The total duration of the examination is likely to be approximately 60 minutes. If you become uncomfortable, we can stop the scan and help you get comfortable again. We will also offer you a break part way through the examination. After the examination you will have your temperature retaken. Your images will be reviewed by a radiologist and any information considered to have clinical value will be sent to your responsible clinician who will discuss it with you. We will also send a letter to your GP to inform them of your participation in the study. We will give you a copy of the MR images of your baby.

You may like to go online and watch a short video explaining the procedure for a fetal MRI in more detail and what you can expect when you come for your scan. While this video describes specifically a fetal MRI for acquiring images of the brain of the baby, the procedure used for this study is very similar: Please find the video by searching 'connectome fetal scanning' on YouTube or click on the following link: **Having a fetal MRI**



Ultrasound scan
We will also invite you to have an Ultrasound scan (before or after your MRI scan), performed in the same way as your routine ultrasound scans earlier in pregnancy The scan will take approximately 30-40 minutes. The results from the Ultrasound scan will be given to you on the day. If there is any information that is considered to be clinically important this will be shared with your midwife and responsible obstetrician who will discuss it with you.

Blood sample
During your visit to St Thomas Hospital, we will also collect, store and later analyse a blood sample of 10 mls max, equivalent of 2 teaspoons. The blood sample will only take a few minutes and will be coded with a unique study number and it will be disposed of after analysis.

Placental analysis
After your baby's birth we seek your permission to collect your placenta. It will be assessed by a placental pathologist under the microscope. This will be undertaken at the hospital where you give birth (St Thomas or UCLH) pathology department as part of the normal clinical services. Placental samples will be stored in the pathology department with your unique participant code so you cannot be identified. All collection, storage, analysis and disposal of samples, after analysiswill be in accordance with the Human Tissue Act. We will compare this information to the data we acquired from your placenta prior to delivery using MRI. We also seek your permission to acquire MRI of your placenta post-delivery for comparison with the pathological examination.

Birth outcomes
We seek your permission to assess your birth records within the hospital or with your GP, to check that you and your baby are both at home. We would like to contact you around 10 weeks post birth to see how you and your baby are doing and specifically to find out a little more about your emotional and physical health and whether you are experiencing any problems. We would like you to record this information in an online questionnaire.

We will send you an electronic link to complete a short questionnaire. This takes approximately 10-15 minutes to complete. It will include questions about your birth experience and yours and your baby's health and wellbeing. You can complete the questionnaire on your phone, tablet or computer. A paper copy is also available if you prefer or the answers can be taken over the phone by our research team.

Summary of study details for participants
The following table summarises the information given above.

Study Time point	Screening and safety questionnaire	Written Consent	MRI with ultrasound scan sensor	Ultrasound scan to check baby's growth and blood flows	Blood sample	Placenta collection	Post delivery phone call and health check questionnaire
Visit 1	x	x	x	x	x		
Visit 2 (optional)	x		x	x			
Visit 3 (optional)	x		x	x			
Post delivery						x	x

All MR assessments will take place at St Thomas' Hospital. Participants booked at UCLH will be consented at UCLH and may have their ultrasound at UCLH.

Expenses and payments
Reimbursement arrangements are in place for local travel costs covering TFL zone 1-6 on the day of your MRI scan, should this not coincide with a scheduled hospital appointment. You will be required to provide copies of your receipts to process reimbursements. Lunch vouchers are available on the day. In rare circumstances we will be able to pre-book transport for participants who are unable to afford the cost.

As a token of our appreciation, we will also provide you with a baby blanket or similar item.

What is being tested
We have used many of these imaging techniques both clinically and in previous research studies. For this study we will also be testing the ability of an MRI compatible Doppler Ultrasound system during the scan to give us information about the baby's heartrate, movement, and response to prelabour contractions.

What are the side effects of taking part?
MRI is a safe imaging technique to use during pregnancy and is routinely used in clinical practice. There are no documented side effects to mother or baby as long as radiological guidelines are followed (which we do).

The MR technique uses a large magnet and radio waves. We will use strengths of the magnet which are safe in pregnancy. 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 necessary to keep certain metallic objects away from the magnet. We have to check that you do not have any metal attached to you, outside or inside your body. In our initial conversations with you we will ask you about the presence of any metal or recent operations which may mean we may not be able to offer you an MRI scan. Unfortunately, this would mean that you would not be able to take part in the study.

The MRI machine is comfortable with a wide central opening and is well tolerated by women in the late stages of pregnancy. However it may not suit you if you suffer from claustrophobia (fear of small spaces), particularly if you are unable to get into a lift (elevator). Once you have been moved into the scanner your head will be level with the opening and not remain deep in the scanner. The magnet is usually wide enough to comfortably scan those with a higher BMI, twin pregnancy or those who are nearing term.

To ensure you are as comfortable as possible, we will give you pillows and take time to carefully position you at the start of the scan. We will also offer you a break during the scan where you can get up and walk around before continuing with the remainder of the examination.

When the machine is taking pictures it is noisy (different beeping noises) but we will provide you with headphones and you can choose your music. The level of noise reaching your baby is dampened by your amniotic fluid and surrounding tissue and we have optimised the way we scan to minimise noise levels. Published studies do not report hearing issues in babies that were scanned as fetuses.

What are the possible disadvantages and risks of taking part?

The examination is not believed to have hazards associated with it for you and your baby, when operated within National Medicine and Health Care Products Regulatory Agency (MHRA) Guidelines (which we do). Some may feel uncomfortable during the scan, but we will try and maximise comfort at the start with the aid of positioning and pillows. The scan may be stopped for a break or repositioning at any time, but in the event that this does not improve the experience the scan can be discontinued.

What are the possible benefits of taking part?

The MR images that we take are for research but might be of benefit to you in improving the information gathered to help take care of you and your baby during your pregnancy. Especially if there are incidental findings, not previously detected (see below). Otherwise, the benefit is likely to be in improving the diagnostic technique for pregnant women in the future.

What if we find something unexpected?

Any imaging study may highlight unexpected findings and it is possible we identify something new in yourself or your baby. We have a set protocol for such circumstances. If we find anything that we consider to be clinically important for you or your baby, we will discuss this with you and refer you for an appropriate consultation.

We may detect certain issues that are important for the management of your current pregnancy such as fetal position in breech or transverse, or a very low placenta, as it is possible that this may impact how you can safely give birth. We will then share this with you and your doctor and midwife.

Otherwise, the study aim is to understand which factors that we can measure prior to labour will give best information on the likelihood of an uncomplicated vaginal birth. These factors will then be used in the future to help women decide on the optimal birth for themselves and their baby. This information may therefore be available to you in a subsequent pregnancy.

What if new information becomes available?

If there is new study information, the patient information sheet and consent form will be updated to reflect the changes and you will be asked to review it and re-consent if you are still happy to continue taking part in the study.

What happens when the research study ends

The data acquisition for this research study will continue for 48 months 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 new MRI techniques to assess fetal and maternal wellbeing in a comprehensive way with the specific aim to be able to provide better information for birth.

We will store personal data collected from this study for over 3 years and research data for 25 years after the study has ended.

What if something goes wrong?

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 [Prof Mary Rutherford email: mary.rutherford@kcl.ac.uk]. If you remain unhappy and wish to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

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?

- We take the safety of your data very seriously. All the research data that we collect (i.e. MR images, blood analysis, questionnaires etc) will be de-identified (all identifiable information removed) and pseudo-anonymised (a unique ID used for each participant). They key to link the unique ID to your name, is held behind a firewall in the hospital system with restricted access to nominated individuals as part of the research study.
- All personal information that is collected about you and your baby during the course of the research will be kept strictly confidential and is covered by the UK General Data Protection Regulation (GDPR). Electronic information is stored behind a firewall on the hospital system and your 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. This information would be given to us by your obstetrician and would be handled confidentially. Any personal data will be processed by KCL University researchers only so will stay inside the UK and be protected by the requirements of the UK GDPR. Your data collected for this study will in addition be fully de-identified and pseudo-anonymised and may then be shared with collaborating units, including those outside of the EU who will be asked to sign a data sharing agreement.
- Any published findings and outputs will also be non-identifiable.

The data will also be extremely useful to scientists and doctors working to understand about the baby and placenta during pregnancy and after delivery, and we would like to make the de-identified and pseudo-anonymised data freely available to them to use indefinitely: This data will be used responsibly and only for the advancement of science and medicine. The raw anonymised (can never be linked to a person) DUS data will be shared with the manufacturer for limited non-commercial purposes in connection with the research project. Further details on the use of your data are given at the end of this form.

As Sponsor King's College London has a responsibility to keep information collected about you safe and secure, and to ensure the integrity of research data. Specialist teams within King's College London continually assess and ensure that data is held in the most appropriate and secure way. This may include storage of anonymised or pseudonymised data with a contracted GDPR compliant third-party storage provider within the UK, where they are assessed as the best data storage option. In such cases the third-party storage provider will not have access to any data that could directly identify you.

What will happen to the results of the research study?

The anonymised results are usually published in the medical literature. No patients' names will be included. Participants can access the results of the study on the study webpage http://www.mibirthstudy.com

Who is organising and funding the research?

The research is funded by the Medical Research Council. The research has been organised by researchers at King's College London, University College London and Guy's and St Thomas' NHS Foundation trust.

Who has reviewed the study?

This study has been reviewed by the GSTT R&D Governance office before it was submitted and reviewed to the London-Harrow Research Ethics Committee and HRA. The study was discussed with the PPI group at St Thomas' Hospital.

Contact for Further Information about this research project:

Mary Rutherford
Professor of Perinatal Imaging
Perinatal Imaging & Health
King's College London
1st Floor South Wing
St Thomas' Hospital
London SE1 7EH
mary.rutherford@kcl.ac.uk

UK General Data Protection Regulation (GDPR) – Patient Information on Data Use

KCL and GSTT are joint data controllers for this research project. For more information, including your legal rights and what to do if you wish to make a complaint regarding the handling of your personal data, please see the GSTT and KCL research privacy notices linked to below.

How will we use information about you?
We will need to use information from your medical records for this research project.
This information will include your initials, NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure, it will be retained for a maximum of 30 years. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from NHS records, your hospital and your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

- For more information please see the following privacy notices:
- GSTT: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx
- KCL:www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research
- HRA: www.hra.nhs.uk/information-about-patients/

Or contact the following:

- For GSTT: Nick Murphy-O'Kane, Contact: DPO@gstt.nhs.uk .
- For KCL: Olenka Cogias, Contact: info-compliance@kcl.ac.uk