



Evelina
London

Guy's and St Thomas'
NHS Foundation Trust



Participant Information Sheet (CONTROL)

The Placenta-Cardiac Imaging Study (PLACARD)

Invitation to take part

We are inviting you to participate in a research study which involves additional ultrasound and/or MRI scans for pregnant women, and additional follow-up for their babies after they are born. 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.

What is the purpose of this study?

By using advanced ultrasounds and MRI scans in pregnancy, we hope to generate a deeper understanding of how the baby's heart, brain and placenta develop together in the womb. These "advanced" scans still use normal ultrasound and MRI machines but generate more detailed information by using newer methods to acquire and process the scan images. For some women, we will also offer an additional heart ultrasound for their child (echocardiogram) at around 1 year of age. Our hope is to use this information both to develop better diagnostic tests for women and families when a problem is suspected during pregnancy, and to understand more about how a baby's environment before birth might shape their future health.

Why have I been invited?

We are inviting pregnant women who have had a normal "20-week" scan to participate, via our antenatal clinics, self-referral, or if they have previously participated in our research. This is because we need to study pregnant women from different groups to understand how these factors vary, in both health and disease. Our main criteria for recruiting participants are:

1. Pregnant women who are at least 18 years of age, and at least 18 weeks into their pregnancy.
2. Women who can read this information sheet, understand the study, and what it would involve for them.

What do I have to do?

You will be invited to come to the hospital for two extra scans (an ultrasound scan and an MRI scan) at two different timepoints during the pregnancy (up to four extras scans in total). Each pair of ultrasound and MRI scans will be performed on the same day whenever feasible, and we will always agree the exact times with you in advance. Some women may only be offered one set of scans depending on their individual circumstances. During the ultrasound and MRI scan we may also give you extra oxygen by facemask, whilst we are taking images of you baby.

What will the scans be like?

The ultrasound scan will last for up to 60 minutes and will be performed by a trained fetal sonographer or fetal specialist. This will be very similar to the ultrasound scans you have already had during pregnancy, and the technology is the same. The MRI scan will also last up to 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 halfway 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. 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>. Once the ultrasound and the MRI scan have started, we may place a face mask on in order to start giving you oxygen. This may continue until the end of the scan.

Why might I be asked to breathe extra oxygen during my pregnancy scans?

We know that breathing in extra oxygen produces some very subtle (but temporary) changes in the baby's circulation. In pregnancies where there is a problem with the placenta or the baby's heart, for example, these changes may be different to those seen in healthy pregnancies. Understanding the differences could help us detect more subtle problems than ultrasound or MRI images could by themselves.

Is it safe to give oxygen during my scans?

We breathe oxygen all the time, and giving extra oxygen is completely safe. Giving extra oxygen to pregnant women is something that has been studied before, and there is no evidence of any negative effects on mothers or their babies, before or after birth.

How long will I be given oxygen for?

We may ask you to start breathing oxygen at any stage during the scan, up to the point when the scan has finished. The maximum time for a single ultrasound or MRI scan is around 60 minutes. Once we are finished taking images of your baby, we will remove the oxygen mask and turn it off. The oxygen levels in your baby's body will return to normal within a few minutes.

How is the oxygen given?

The oxygen will be given via a plastic mask with a small plastic bag attached to the front. The mask will be fitted over your ears when it is time to give the oxygen.

What will it feel like?

You may feel the oxygen blowing out of the mask. It doesn't matter if some leaks out around the sides. If you feel that you are getting a very dry nose or mouth, or the mask is uncomfortable, the team will be around you at all times - just let them know.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Please read this information sheet to help you to decide. If you do decide to take part, you will be asked to sign a consent form. You are free to withdraw at any time and you do not have to give a reason. Whatever decision you make, it will not affect how either you or your baby are looked after.

What are the side effects of taking part?

Ultrasound scans, MRI scans and maternal oxygen are not believed to have any side effects for you or your baby. The MRI scan will take place in an enclosed machine, and it is important to be aware of the following points:

- People who suffer from claustrophobia and cannot travel in a lift as a result may find it difficult in the MRI scanner; if this is the case you will not have to take part in the scan.
- Occasionally we find that the MRI is not wide enough to take some women.
- 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 very effectively reduced when going through your body and is much lower for the baby than it is for you.
- Some women start to feel warm once they are inside the scanner, so we will have a fan on 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 ultrasound scan and MRI scans, but where possible we will book these on the same day, or in combination with other medical appointments if you have them. We will also always try to work with you to find the most convenient time(s) for you to attend, based on your circumstances.

What are the possible risks of taking part?

Fetal ultrasound has no known risks, and there are no additional risks to your baby or long-term effects of having the MRI scan. We operate within National Radiological Protection Board Guidelines for all MRI scans. Maternal oxygen has also been shown to be safe to pregnant women and their babies - even when given for much longer periods than we are doing in our study. There are some patients in whom care should be taken before giving oxygen, such as those undergoing active chemotherapy or those with severe chronic lung disease. We may ask you about this before we recruit you into the study. If you think either of these apply to you, please discuss this with one of our research assistants.

What are the possible benefits of taking part?

If you wish to take part in the study, you will be shown images from the MRI and ultrasound by one of our researchers in a 5-10 minute session after the scans. You are welcome to take pictures (for example from a smartphone) during this time. 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 specialist antenatal clinics nationally.

What if new information becomes available?

There is always a possibility that additional scans might show information that was not seen previously. If there is any additional information, the findings will be communicated to you and your clinical team as soon as possible. This will allow your doctor to advise you on the management of your pregnancy with all available information.

What happens after the pregnancy?

Immediately after the pregnancy we will offer to perform a detailed examination of the placenta, if you have provided the optional consent for us to do this. This process is entirely managed by our research team with no action needed by you after the delivery. The placenta will be analysed by existing clinical teams in the hospital and will be labelled with identifiable information (for example your name, date of birth, NHS number) until this has been completed. These details will be visible to the clinical teams performing the analysis so that the results can be added to your clinical records. Once this process is complete, the placenta will be disposed of in accordance with the Human Tissues Act. If you do not consent for a placental analysis, the placenta will be disposed of in the usual way after the pregnancy ends in line with local clinical practice.

If appropriate, we will also contact you to offer an optional follow-up appointment for your baby at around 1 year of age. This would involve an examination of your child and an ultrasound of their heart. All follow-up for your baby will be clearly explained to you again after your pregnancy ends and will only proceed with your permission, even if you have already had additional scans in pregnancy. Finally, if your baby has scans as part of their own clinical care, we may also request the results of these scans to compare to the images we have taken before birth.

What type of scan will my child be offered, and is it safe?

An echocardiogram is a specialised ultrasound scan of the heart and blood vessels. It is the same technology as the ultrasound scans used in pregnancy and is completely safe. The scan will be performed by an expert sonographer from the paediatric cardiology team at the Evelina London, who will have extensive experience in scanning children of all age groups.

What happens when the research study stops?

This research study will continue for at least five years, and we hope it will provide valuable results, which we will publish in research journals. No patients' names will be included.

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, or contact us using the details below. 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 020 7188 7188, 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. Members from the research team and appropriate bodies and regulatory authorities will have access to participant medical records, and permission for this will be requested in the consent form. 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 and will only be kept for up to five years from the date you consent to the study. We will always remove personal information from any imaging data used outside the Trust.

Am I able to claim any out-of-pocket expenses for these additional scans?

Yes, we can offer £15 towards your travel costs for each additional day you visit the hospital.

How long do you keep the data from my scans?

We will keep the data from each participant for 25 years. If a participant were to lose capacity after consenting, we would also keep this data, however no new data would be collected. Where participants withdraw consent, we keep data already collected and do not collect any further information. If you agree to be contacted about similar research projects, we may keep your personal details as well so that we are able to get in touch in the future, but we wouldn't keep this type of information for longer than five years from the date you consent to take part in the study.

How will we use information about me?

We will need to use information from your extra scan and your medical records for this research project. This information will include your:

- Full name
- NHS number
- 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. 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 my choices about how my 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 already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital and/or 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 won't 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 I find out more about how my information is used?

You can find out more about how we use your information

- by asking one of the research team
- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by sending an email to **info-compliance@kcl.ac.uk**
- by ringing us on **02071889145**

Will you share my information with anyone else?

Any data from the scans will have any personal information to connect the data to you removed (name, address etc.). This anonymised data will then be used for the data analysis and may also be shared with collaborating researchers in other units. Users of any of the data collected as part of this study will be asked to sign a declaration that they will use the data responsibly and only for the advancement of science and medicine. We will also ask for your permission to share information about your participation with your GP and/or other medical staff involved in the care of you or your baby. 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.

Who is organising and the research?

The research is organised by and Kings College London and Guys and St Thomas' NHS Foundation Trust.

Who has reviewed the study?

The study has been reviewed by REC 24/WS/0051.

Contacts for further information

Name: **Dr David F A Lloyd MBChB, PhD**

Address: Department of Perinatal Imaging, King's College London, 1st Floor,
South Wing, St Thomas's Hospital, London, SE1 7EH

Tel: **0207 188 9145**

Email: info@placard.study