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KING'S College LONDON

Advanced cardiovascular assessment in pregnancy

Information sheet for participants

Invitation

We would like to invite you to take part in this research study. This leaflet explains why the research is being done and what taking part in the study would involve. Please feel free to contact us if you have any questions about the study.

Part 1 tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?

During pregnancy, the size and shape of the heart change to accommodate the extra demands for the growth of the baby. This study will help us understand whether by studying your heart we can improve the prediction for complications at the end of the pregnancy.

Why I am invited for this study?

Pregnant women attending for routine fetal assessment in the first, second or third trimesters are invited to take part in the study, that will help us to understand how the heart function is coping as pregnancy progresses.

Do I need to take part in the study?

You are under no obligation to participate. If you agree to participate, we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw your consent at any time, without giving a reason.

What will happen if I take part?

After we complete your routine scans, we will ask your permission to carry out an extra measurement on the function of your baby's heart and a scan of your heart called echocardiogram. Essentially, we will place 3 stickers on your chest to monitor your heart rate and then use the ultrasound probe (same as looking for your baby) to take some views of your heart. This test lasts for about 10 minutes. We will then place two small probes on your index fingers and measure blood flow during measurement of your blood pressure with a cuff round your arm (this examination takes about 10 minutes). We will also place two small cuffs one around your neck and one around your thigh to assess the pressure waveforms in the neck artery (carotid artery) and at your thigh (femoral artery). The recording lasts for 10 seconds. You will not feel any pressure or other sensation with the placement of the cuffs. Finally, we will ask you to take a photo of your right eye with the eyes open using a special camera. This test will provide information about the size of your vessels in your eye and will inform us about the health of your vessels in the rest of the body. We will also ask you to doppler the main artery in both eyes by gently touching your right eyelid with your eyes closed with the ultrasound probe. The test takes 1min and there is no

associated discomfort to it. During the visit a blood sample will be collected to analyze biomarkers and analyze your risk for pregnancy complications. A small amount of blood will be stored for future analysis.

You are being invited to take part in a research study evaluating a new AI-assisted ultrasound system designed to help acquire ophthalmic artery Doppler measurements. The procedure involves a non-invasive ophthalmic artery Doppler ultrasound scan. A small ultrasound probe will be placed gently on the closed eyelid using ultrasound gel. The AI-assisted system will provide real-time guidance on probe positioning and will automatically acquire the Doppler measurements. This phase of the research is a technology validation study and will take place before the system is used in future studies involving pregnant participants. This procedure is non- 1 of 3 invasive and uses ultrasound, which is routinely used in clinical practice. There are no known risks associated with this type of examination. The data from the ophthalmic doppler is analysed using validated research methods to evaluate flow characteristics in the ophthalmic artery and to determine the performance of the AI-assisted system.

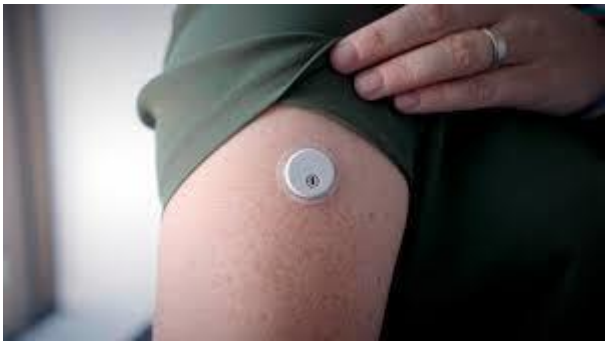
You will be asked to undergo a brief, non-invasive retinal imaging examination. This involves taking photographs of the back of your eye (the retina) to assess retinal structure and overall eye health. High- resolution images will be taken of different parts of the eye, including the optic nerve, macula (central retina), peripheral retina, and retinal blood vessels. The images will be captured by trained members of the research team using standard retinal imaging equipment that is routinely used in clinical eye examinations. The procedure is painless, does not involve any contact with the eye, and usually takes around 5–10 minutes to complete. You will be asked to sit in front of the imaging device and look at a light while the images are taken. The retinal images will be stored securely on encrypted, access- restricted research servers in line with King's College London and NHS data protection requirements.

We will also be collecting saliva samples. The sample will help use to understand how lifestyle and hormonal changes may affect health at different stages of a woman's life, such as before pregnancy, during pregnancy, after birth, and around menopause. You will be asked to provide a small saliva sample using an at-home collection kit. This is painless, non-invasive, and does not involve blood tests or clinic visits. The saliva sample is used to look at genetic information you are born with, as well as markers that can change over time and reflect how factors such as lifestyle, stress, nutrition, hormones, and ageing are influencing your body. The results are used to support personalised lifestyle guidance, such as advice on diet, physical activity, sleep, and stress management. In some cases, saliva testing may be repeated over time to see how the body responds to lifestyle changes. Taking part involves minimal burden and no additional clinical risk.

Body composition and autonomic nervous system function will also be assessed during your visit. The assessment will measure fat mass (FM), fat-free mass (FFM), total body water (TBW), intracellular water (ICW), and extracellular water (ECW), heart rate variability (HRV) and stress response and recovery patterns. Four electrodes will be placed on you right foot and right arm and sensors will be placed on your right and left index finger. The assessment will take between 10-15 minutes.

We would be grateful if you would be willing to come with your child to our unit within the first 5 years after the birth of your baby to repeat the scan for your heart, measure your blood pressure and the blood flow in your fingers. We may ask you to perform home monitoring of blood pressure or 24-hour blood pressure recording depending which one is more convenient to you. If you are willing to provide a blood test, we will assess your cholesterol and other blood markers. We would also like to measure the weight, height and perform an echocardiogram to your child. We will reimburse your expenses for this visit.

You may be asked to wear a blood sugar monitoring device for up to 14 days. The device measures changes in your blood sugar over time and may give us important information about your heart and blood vessel health and blood sugar control now and in the future. The device is shown below.



The research team will be able to show you how to put the device on. You can do all your usual activities wearing the device including bathing, showering and swimming. After 14 days we would like you to remove the device by gently pulling it off your arm and to return it in a stamped addressed envelope provided. You do not need to link the device to your phone or any other electronic device. All the data is stored within it and will be linked with your study ID.

Are there risks and discomforts?

There are no risks related to this study for yourself or your child. You and your child will not feel any pain or discomfort with the echocardiogram. When we inflate the blood pressure cuff on your right arm, you might feel a tingling sensation in your fingers but this feeling wears off very quickly.
There is always a risk of a small bruise following the blood test, but this will be minimized by the sample being taken by an expert practitioner.
There might be slight discomfort on insertion or removal of the blood glucose monitoring device.

What are the potential benefits?
There are no immediate benefits to you in the current pregnancy. Imaging of the fetal heart does not provide information on the anatomy of the heart which has been assessed as part of clinical work. However, we hope that the information we obtain from the study will improve our understanding of pregnancy complications and help in the development of methods to prevent such complications.

The examination that will be carried out after the birth of your baby could identify certain problems, such as high blood pressure, heart strain or high cholesterol level in your blood. Subtle cardiac changes might be identified in your child. **In such case we will inform you and your GP because further assessment and treatment may be necessary**.

What happens if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm your child might suffer will be addressed. Detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes, we will follow ethical and legal requirements and all information about you will be handled in confidence. In case that an abnormality is identified during your cardiac assessment whilst pregnant we would like to inform your GP to refer you for further investigations. The details are included in Part 2.

This completes Part 1 of the leaflet. If the information in Part 1 has interested you,

please read the additional information in Part 2 before making any decision.

Part 2

What if there is a problem?
If you have a concern about any aspect of this study, firstly you should ask to speak with the researchers, who will do their best to answer your questions. Any complaint about the way you have been dealt with during the study will be addressed. If you remain unhappy and wish to complain formally, you can contact the local Patient Advice and Liaison Service (PALS) at 020 3299 3601 or email kch-tr.PALS@nhs.net.

In the unlikely event that something does go wrong and you are harmed by taking part in the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King's College London. King's College London has obtained insurance which provides no-fault compensation i.e. for non-negligent harm and you may be entitled to make a claim for this.

Will my information in the study be kept confidential?
Yes. It will not be possible your details and study results to be identified outside of the study group. Every participant will be given a unique study number and only those codes will be used by the laboratories. We will not disclose your personal data to any other investigators.

What will happen to any samples given?
We will ask for your permission to save some of your blood sample which will be stored for further research. Care will be taken to make sure that the blood samples are anonymized and only the principal investigators and responsible fellow will have access to the stored blood samples.

What will happen to the results of the research study?
All scientific results will be published in journals and presented at academic meetings. You will not be identified in any of the reports or presentations.

Who is organizing and funding the research?
This study is being arranged by King's College London and King's College Hospital NHS Foundation Trust and funded by Fetal Medicine Foundation.

Who has reviewed the study?
Medical research is looked at by an independent group of people called a Research Ethics Committee to make sure that your safety, rights, wellbeing and dignity are protected. This study has been reviewed and given a favorable opinion by the research ethics committee.

Who can I ask for more information?
If you have any questions about the tests, please contact:
Dr Marietta Charakida, via e-mail (marietta.charakida@kcl.ac.uk) or by calling 020 7188 5444.Tanvi Mansukhani via email (tanvi.mansukhani@nhs.net or by calling 020 3299 7351).

If you would like independent advice as to whether you should participate we recommend that you take this information sheet and discuss it with your family doctor and ask him or her if they could recommend somebody who might provide independent advice. Alternatively, you could approach the doctors leading the research who would be happy to try and arrange an independent person to talk to you.

Thank you for taking the time to read this information leaflet