Chief Investigator: Professor Asma Khalil

Principal Investigator: Dr Kelsey Lennox

Title: Routine Use of Focussed Point-of-care Ultrasound for Antenatal Fetal Imaging

Short Title: RUFUS-AFI

We would like to invite you to take part in our study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us.

What is the purpose of the study?

The study aims to find out whether a small handheld point-of-care ultrasound (POCUS) device can be used alongside the standard hospital ultrasound in antenatal care, and whether people find this acceptable. We will compare measurements from both devices, and how long each scan takes to check how reliable and efficient handheld ultrasound is in routine care. The results will help us plan a larger future study.

The study will include 280 pregnant patients who meet eligibility criteria and are attending Liverpool Women's Hospital. 180 participants who are attending routine ultrasound appointments will undergo both POCUS and standard ultrasound scans conducted by the same sonographer. 100 participants who are attending for planned birth will have sweep cineloops taken. 100 participants who are attending for assessment of multiple pregnancy will have sweep cineloops taken. The POCUS ultrasound scan will be performed by a hand-held device that is CE marked for use in the UK. Data from these scans will be analysed to assess measurement reliability, scan duration, and efficiency. If successful, this research

could support the integration of POCUS into routine obstetric care, potentially enhancing service efficiency and accessibility for high-risk patients.
If later research confirms handheld scans are reliable, this could help the NHS deliver scans more efficiently. We are not measuring costs in this study.

Why have I been invited?

You have been invited because you are receiving antenatal care at Liverpool Women's Hospital and are booked to give birth at Liverpool Women's Hospital (or will receive intrapartum/postnatal care here), which allows us to collect routine outcomes from your records after birth.

Your care team have recommended an ultrasound to assess your baby's growth in pregnancy. This could be:

- because you have diabetes,
- because your baby has been moving less than usual,
- or because your baby is smaller than expected.

You may also be invited if you are booked for a planned birth at Liverpool Women's Hospital, or because you are having an ultrasound assessment of multiple pregnancy (twins, triplets, or more). In these groups, we collect a very short ultrasound video ("cine loop") during the handheld scan, and people having a planned birth will also have measurements taken to estimate their baby's weight; this takes only a few seconds and does not change your care.

We aim to collect information about you and measure your baby using two devices: a standard ultrasound machine (normal care) and a point-of-care ultrasound device. We will compare the measurements between the devices to see if the point-of-care device is reliable. We would also like to know what you think about the point-of-care ultrasound device and scan, and so there is a short survey to complete after the scan.

Do I have to take part?

The answer is 'No': Taking part is entirely voluntary.
If you do not wish to participate in the study, your continued medical treatment will not be affected in any way.

What will happen to me if I decide to take part?

A member of the study staff will explain the study to you when they invite you to participate. You may take as long as you wish to think about participation, and we can book an appointment on a separate day to allow you time to consider. In this case, please contact the team once you have decided you would like to participate.

If you agree to take part, you will sign a consent form, and the study staff will collect the required data from your pregnancy care records, perform the ultrasound scans and log them in our secure data system. This can include your height and weight, the number of babies you have had and how you birthed them along with any pregnancy complications, whether this is a spontaneous conception or IVF, and if you have any medical conditions or past operations currently affecting your pregnancy care. During your scan, we will also record a short ultrasound video (‘cine loop’) of a gentle sweep across your abdomen. This takes only a few seconds and does not change your care. Following the scans you will be provided a short experience survey.

What should I consider?

You must be 18 years old and above to participate. If you lose the ability to give informed consent during the study, you will be withdrawn from the research. However, any information collected up to that point will still be used to ensure the research remains valid.

Are there any possible disadvantages or risks from taking part?

The scan appointment may take slightly longer than usual, as it will involve two short scans. The video adds only a few seconds to your scan, so the overall impact on your appointment is very small. This study will not change any aspect of your or your baby’s care, which will be in line with local protocols.

Will my taking part in the study be kept confidential?

Any information that is collected about you during this research will be kept strictly confidential and on a secure database. We will use a study participant number instead of any personal details. No individual participants will be identified when the results of the study are published. Responsible members of Liverpool Women’s Hospital and the Harris

Wellbeing of Women Research Centre may be given access to data for monitoring and audit of the study to ensure that the research is complying with applicable regulations.

We will not routinely inform your GP of your participation in this study. If a letter is to be sent, we will ask for your permission first.

Will I be reimbursed for taking part?

The sonographer will provide you a complimentary scan picture of your baby. Pictures of specific features may not be possible due to fetal position, but the sonographer will try their best.

What will happen to my data?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- Initials
- NHS number and hospital number
- Name
- Date of birth

People will use this information to do the research or to check your records to make sure that the research is being done properly. Those 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.

The University of Liverpool is the sponsor of this research.

The University of Liverpool is responsible for looking after your information. We will not share your information related to this research project with other organisations.
We will keep all information about you safe and secure by:

- Keeping your personal details (such as your name and NHS number) separate from your research data.
- All information collected will be given a unique study ID number instead of your name.

- Paper consent forms will be stored in a locked cupboard in a secure research office.
- Electronic data (e.g. questionnaire responses, scan measurements) will be stored on secure, password-protected systems.
- Access to your data will be limited to authorised members of the research team.
- Ultrasound images and short video clips will be stored securely and labelled only with your study ID. We will remove any built-in labels or identifiers before saving them. We will keep your research data for at least 10 years, as required by research guidelines.
- Any published results will not include information that could identify you.

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

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.

We will keep your study data for at least 10 years. At the end of the study, we will permanently remove the code that links the study number to you. This means your pictures, videos and data cannot be linked back to you. These anonymised datasets may then be kept for use in future research, but no information that could identify you will ever be included. Some future projects may use the anonymised images and short videos from this study to develop or test computer methods (‘artificial intelligence’) that analyse ultrasound. These projects would use anonymised files only, with no way to identify you, and would not affect your care.

What will happen if I do not want to carry on with the study?

Participation is voluntary, you may change your mind at any later stage. Withdrawal will not affect the care you receive from the NHS.

If I decide to withdraw, the information collected up to that point may still be included in the study, because researchers are required to use data collected before withdrawal.

What are your choices about how your information is used?

Taking part in this study is completely voluntary. You can change your mind at any time and withdraw from the study without giving a reason. This will not affect the care you receive in any way.

If you choose to withdraw, we will keep the information collected about you up to that point. This is because removing data could affect the overall accuracy and reliability of the research. Keeping this data is allowed under UK data protection law and is recommended by the Health Research Authority.

You can choose to stop taking part at any time by letting a member of the research team know.

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

You can find out more about how we use your information through the HRA link: www.hra.nhs.uk/patientdataandresearch

What will happen to the results of this study?

We intend to publish the results of this study in conferences as well as publications. No individual participants will be identified when the results of the study are published. If you wish, you can opt-in to receive updates about the study and results via an email newsletter, and links to published social media posts about the publications.

After the research has ended, the research data will remain stored on university servers for 10 years. The data will be anonymised and may be used for future studies both by local researchers and in research projects in hospitals, universities, non-profit institutions or commercial laboratories worldwide. We will not share any information which will identify you.

What if there is a problem?

University of Liverpool, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during this study, you should contact Professor Asma Khalil, Chief investigator (asma.khalil@lwh.nhs.uk).

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion.

Further information and contact details:

Please contact Dr Kelsey Lennox by telephone at +447795226291, e-mail Kelsey.lennox@nhs.net, or in writing to Dr Kelsey Lennox, Liverpool Women's Hospital, Crown St L8 7SS.

Thank you for considering taking part in this research.