Sono-breech Participant Information Sheet

Sono-breech study

Diagnostic accuracy of handheld ultrasound in determining fetal presentation at 36 weeks gestation

Co-Chief Investigators:

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You are being invited to take part in a research study, called the Sono-breech Study. This leaflet is to help you decide whether to participate. It tells you why this study is being conducted and what taking part will mean for you. Please take time to read it carefully. You may also get in touch with the study team if anything is not clear or if you would like more information. Take your time to decide whether or not you wish to be involved.

If you decide not to take part your future care will not be affected. If you do take part but decide later on that you don't want to after all, you can withdraw at any time – you do not have to give a reason and your care will not be affected.

Thank you for reading this.

What is the purpose of the study?

Most babies are cephalic (head down) at the end of pregnancy, however 3-4% of babies are breech (bottom down). At a late pregnancy check, midwives feel a woman's tummy (abdomen) using their hands (palpation) to check for the baby's position but up to 40% of breech babies are missed. Being specific about the baby's position is particularly important so that plans for safe delivery can be made. Breech babies are at higher risk of injury during normal birth than cephalic babies. Undiagnosed breech births can be associated with poor outcome for baby and mother, so determining which way the baby is positioned is important to provide women with the information they need in order to make an informed choice about their care.

The 'gold standard' for determining a baby's position is by ultrasound scan. This is performed by a trained person called a sonographer or a specialist doctor using a hospital-based ultrasound machine. In recent years, smaller ultrasound machines have been introduced into some clinical areas to help diagnose conditions where a conventional ultrasound is not present. An advantage of these machines is that they are portable. These machines connect to a mobile phone or e-tablet. We want to know if midwives are able to tell what position your baby is in before it is born using a small

ultrasound machine and to see if this is in agreement with a conventional scan used in hospitals. We also want to know what maternity service users think about the use of these devices, whether these devices will reduce the risk of undiagnosed breech presentation and its potential complications, and in turn whether this will save money for the NHS.

Why have I been invited?

All women who are around 36 weeks (35^{+0}-36^{+6}) pregnant with one baby (not a twin) are eligible to take part in this study. Over 9000 pregnant women across the UK will be invited to participate in this study.

Do I have to take part?

No. It is your choice. If you are willing to be part of the study, you will be asked to complete a consent form. If you prefer not to take part, tell your doctor or midwife and we will not ask you again. 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 in the future.

What will happen to me if I take part?

Pregnant women who are between 35^{+0}-36^{+6} weeks pregnant with one baby will be invited to participate in the study by a midwife at their 36-week appointment. At this point we will ask your permission to collect information about you and your baby – this is called taking consent.

<u>36-week appointment</u>

If you agree to participate in the study at your 36-week appointment, your midwife will record some basic information about your pregnancy in a secure password-protected database. They will perform a routine examination, which includes feeling your tummy to determine your baby's position and checking your baby's heartbeat using a handheld device. This part of the examination would be exactly the same whether you take place in the study or not. The midwife will record their findings.

The midwife will then use the handheld ultrasound device to check your baby's position and heartbeat. The ultrasound device will be placed on your tummy, similar to the scan you had at 20 weeks. The ultrasound probe connects to a device with a screen, which may include a mobile phone, e-tablet or laptop. The midwife will record their findings. The appointment should not take more than 30 minutes longer than a usual routine appointment.

<u>Confirmation scan</u>

After this, either later the same day or before the end of the next day, you will receive a scan using a conventional ultrasound machine, performed by a trained sonographer or specialist doctor. This scan may be a planned growth scan (depending on your care pathway, your pregnancy and any risk factors) or it may be an additional scan. This may take place in the ultrasound department, or in the maternity day assessment unit or antenatal clinic, depending on availability in your hospital. This scan will help to

confirm your baby's position and compare the results between the two different ultrasound machines. It is important not to miss the conventional scan, otherwise your results will be excluded from the research study.

What happens next

If your baby is head down, your care will not change and you can continue with your chosen delivery plan, whether that is for a normal birth, induction of labour or planned caesarean.

If your baby is breech, arrangements will be made for a healthcare professional to discuss your delivery plan with you as per your hospital's pathway. There are several options, including external cephalic version (ECV - which involves attempting to turn the baby to head down by applying gentle pressure to the abdomen), planned caesarean section or planned vaginal breech birth. The healthcare professional at your hospital will discuss the options with you, including the risks and benefits of all these options and will support you to make a decision about your delivery that you are most comfortable with.

Birth

Information about the birth, including how you deliver and how your baby is doing initially after delivery, will be recorded in the same secure database. This data will be collected for up to 28 days following the birth.

Questionnaire

Around six weeks after the birth, two online questionnaires will be sent to you via email. The questionnaires will ask some questions about your pregnancy and your baby. If you do not have online access at home, please let your midwife know so that online access can be arranged in your hospital or clinic.

Interview

Between 6-12 weeks after the birth, you may be invited to take place in a short interview, where a member of the research team will ask some questions about how you felt about the study and the use of the handheld ultrasound devices. We would also like to interview some women who choose not to take part in the study, to explore why they preferred not to have the scan. You can decline to take part in the interview. The interview will be recorded for transcription (carried out by a member of the research team) and the recording will be deleted once this is complete. Those participating in the interviews will be given a £25 voucher.

What do I have to do?

Your 36-week appointment will take up to 30 minutes longer than usual. The study may require you to attend the hospital or community clinic for an additional midwife appointment and/or scan. This will not affect the rest of your normal antenatal care. If your baby is detected to be in the breech position, the options will be discussed with you as per the Hospital's pathway.

What are the possible disadvantages and risks of taking part?

Ultrasound, both using conventional machines and handheld devices, is very safe and will not cause harm to you or your baby.
Depending on when and where your midwife appointment and confirmation scan take place, this may involve an additional visit to the hospital; please discuss with your midwife if taking part in this study is restricted by public transportation, distance to the hospital, or parking costs.

There is a small chance that your baby could change position after the scan. If this happens, options will be discussed with you as per the hospital's guidelines.

What are the possible benefits of taking part?

The second scan will confirm your baby's position – this may be a benefit if your baby is found to be breech. If your baby is detected to be breech as part of the study, your care will follow the pathway for breech babies, which may lead to a better outcome than if breech presentation had not been found.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigators (Dr Christoph Lees, email contact: c.lees@imperial.ac.uk and/or Dr Amar Bhide, email contact amar.bhide@nhs.net).

The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team (rgitcoordinator@imperial.ac.uk).

What will happen to the results of the research study?

The results of the study will be published in scientific journals and presented at medical conferences after completion of the study. We are committed to feeding back results of the study to participants and will share results by email. You will not be identified in any report or publication. As this is one of many on-going studies in Queen Charlotte's and Chelsea Hospital, if you consent, we may contact you again in the future to see if you would be happy to take part in other ethically approved studies.

Who is organising and funding the research?

The Sono-Breech study is being carried out by Professor Lees, Dr Bhide and their team. It is also taking place in centres across the UK by members of the Sono-Breech research group. This group is made up of researchers and health professionals who specialise in caring for babies and mothers during pregnancy.

This study is sponsored and organised by Imperial College London, with The Centre for Trials Research, Cardiff University managing the trial on a day to day basis. The trial is being funded by the UK National Institute for Health Research (NIHR).

Who has reviewed the study?
This trial, the participant information and informed consent, has been reviewed by some members of the Sono-breech study advisory group, which includes members of the public involved with patient and public engagement with research. As a result of this, changes were made to improve readability and to ensure all information is as reader friendly as possible.

This study was given a favourable ethical opinion for conduct in the NHS by a research ethics committee.

The IRAS reference number is 318520.

Contact for Further Information

For more information you can contact sono-breech@imperial.ac.uk

Or write to either:
Sono-breech Investigators, Centre for Fetal Care, Queen Charlotte's & Chelsea Hospital, Du Cane Road, W12 0HS, London
Email: sono-breech@imperial.ac.uk

PALS:
If you have any concerns or wish to complain the details of your local Patient Advice and Liaison Service (PALS) are available on your local hospital's website or on www.nhs.uk.

How to keep up to date with Sono-Breech?

Instagram: @**sonobreech**

X: @**sonobreech**

Thank you for taking part in this study.
A copy of the written information and signed Informed Consent form will be given to you to keep.

Transparency notice
Imperial College London is the sponsor for 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 appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

For more information / confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information (including personal data and data created as part of the study) from you for this research project. This information will include your name and contact details.

People within the College and study team (see section 'Sharing your information with others') will use this information to do the research or to check your records (see information to be collected) to make sure that the research is being done properly and the information held (such as contact details) is accurate.

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.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes".

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- Some of your information (your name, date of birth, and contact details) will be shared with other universities involved in the study, namely Cardiff University and University of London. This is to allow researchers to be able to contact you about taking part in another part of the study. This may involve speaking to a researcher or completing some questionnaires. You can take part in these even if you do not take part in the scan.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Samples / data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

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 already have because some research using your data may have already taken place and this cannot be undone.

- If you choose to stop taking part in the study (also known as opting out), we would like to continue collecting information about your health from your hospital record. If you do not want this to happen, please tell us and we will stop. This will not affect any healthcare or support you may be receiving separately.
- We need to manage your records in specific ways for the research to be reliable. This means that we may not be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information:

- by asking one of the research team
- by sending an email to sono-breech@cardiff.ac.uk

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to sono-breech@cardiff.ac.uk

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.