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What is the diagnostic accuracy of midwife-delivered point-of-care ultrasound for detecting breech presentation at term?

Submission date
03/09/2024

Recruitment status
Recruiting

Registration date
30/04/2025

Overall study status
Ongoing

Last Edited
24/09/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

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 outcomes for the 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 handheld 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.

This study aims to find out whether midwives are able to tell what position the baby is in before it is born using a small handheld ultrasound machine and to see if this is in agreement with a conventional scan used in hospitals. The researchers also want to know what maternity service users think about the use of these devices (explored through recorded interviews with selected women and midwives), and 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. The team running the study include experts in trial design and statistics, obstetricians, midwives, sonographers, neonatologists, qualitative researchers and health economists from a number of institutions with direct patient involvement.

Who can participate?

Pregnant women who are between 35+0-36+6 weeks pregnant with one baby, of different backgrounds from collaborating maternity units which are geographically diverse and include the North of England, the Midlands, South Coast, London and the East of England

What does the study involve?
Participants will be invited to participate in the study by a midwife at their 36-week appointment. The researchers will compare handheld ultrasound to the 'gold standard' conventional ultrasound. The conventional ultrasound will need to be performed within one day of the handheld ultrasound.

What are the possible benefits and risks of participating?
Ultrasound, both using conventional machines and handheld devices, is very safe and will not cause harm to the pregnant woman or their baby. Depending on when and where the midwife appointment and confirmation scan take place, this may involve an additional visit to the hospital. There is a small chance that the baby could change position after the scan. If this happens, options will be discussed with the study participant as per the hospital's guidelines.

Where is the study run from?
1. Imperial College London (UK)
2. The Centre for Trials Research, Cardiff University (UK)
3. City St George's (UK)
4. University College London (UK)

When is the study starting and how long is it expected to run for?
May 2023 to March 2027

Who is funding the study?
NIHR Health Technology Assessment (HTA) (UK)

Who is the main contact?
Dr Eleri Owen-Jones, sono-breech@cardiff.ac.uk

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Additional identifiers

Integrated Research Application System (IRAS)
318520

Central Portfolio Management System (CPMS)
53525

Study information

Scientific Title
Diagnostic accuracy of handheld ultrasound at 36 weeks of gestation to determine fetal presentation

Acronym
Sono-breech

Study objectives

What is the diagnostic accuracy of midwife-delivered point of care ultrasound (PoCUS) for detecting breech presentation at term?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/07/2024, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048121; southbirmingham.rec@hra.nhs.uk), ref: 24/WM/0143

Primary study design
Observational

Study design
Multicentre prospective observational study

Study type(s)
Other

Health condition(s) or problem(s) studied
Pregnant women

Interventions
There are three components to the study: the main diagnostic accuracy study; a nested acceptability study using qualitative methodology; and a health economic evaluation to evaluate cost-effectiveness.

36-week appointment:
At routine 36-week antenatal appointments, eligible pregnant women will be consented to take part in the Sono-breech study. They will receive their usual 36-week examination including abdominal palpation to determine fetal presentation and check fetal viability. Following this, the Sono-breech trained midwife will perform a handheld PoCUS scan to check presentation and fetal viability. This should take no longer than 30 minutes.

Following the handheld scan the Sono-breech midwife will arrange for the woman to attend an ultrasound scan performed by an Ultrasound Practitioner on a conventional ultrasound machine within one day. The Ultrasound Practitioner will check fetal presentation, and this will be recorded. This should take no longer than 10 minutes. The conventional ultrasound confirmation must NOT be done on a handheld PoCUS device. The pathway for ultrasound scans will differ from site to site, and liaison with the maternity unit and ultrasound department during study set-up will ensure availability for same/next day ultrasound assessment using a static conventional ultrasound machine.

Questionnaire:
Around 6 weeks after the birth, two online questionnaires will be sent to the study participants via email. The questionnaires will ask some questions about the pregnancy and the baby.

Interview:
Between 6-12 weeks after the birth, some study participants will be invited to take place in a short interview, where a member of the research team will ask questions about how the study

participant felt about the study and the use of the handheld ultrasound devices. The researchers plan to interview some women who choose not to take part in the study to explore why they preferred not to have the scan.

Intervention Type
Other

Primary outcome(s)
Diagnostic accuracy (sensitivity and specificity) of midwife-conducted handheld PoCUS at 36 weeks for the detection of breech presentation compared in the same women to 'gold standard' conventional ultrasound

Key secondary outcome(s)
1. Acceptability to midwives and pregnant women of handheld PoCUS in the detection of breech presentation at term, measured using focus groups (midwives) during the study period; and interviews (pregnant women) up to 12 weeks after birth
2. Resource use including mode of birth and neonatal intensive care unit (NICU) – reasons and outcome of admissions, and length of stay obtained from patient records for up to 28 days
3. Evaluation of training requirements for midwives using handheld PoCUS for fetal presentation, measured using focus groups during the study period
4. Proportion of breech presentations that remain undiagnosed in labour and resulting change in management, measured using a Pregnancy Outcome CRF recorded up to 12 weeks after birth
5. Birth experience measured using the Birth Experience Assessment Measure completed up to 6 weeks after birth
6. Infant quality of life measured using the Infant Quality of Life Instrument (IQI) completed up to 6 weeks after birth

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Singleton live pregnancy
2. 35+0 - 36+6 weeks of gestational age
3. Ability to give valid informed consent
4. Commitment to attend a second scan within 1 day
5. Midwifery sample eligibility – being part of the Sono-breech study and undertaking PoCUS scanning as part of this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

Female

Total final enrolment
0

Key exclusion criteria
1. Multiple pregnancy
2. Unable to attend a second scan within 1 day

Date of first enrolment
05/08/2024

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Charlotte's and Chelsea Hospital
Imperial College Healthcare NHS Trust
London
England
W12 0HS

Study participating centre
St Mary's Hospital
Imperial College Healthcare NHS Trust
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W2 1NY

Study participating centre
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Heath Road
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Study participating centre
West Suffolk Hospital
West Suffolk NHS Foundation Trust
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Study participating centre
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Study participating centre
Northwick Park Hospital
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Study participating centre
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Sponsor information

Organisation
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ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/09/2026	24/09/2026	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes