

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

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Registration date 30/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/04/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 June 2026

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

Study website

https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/sono-breech/_recache

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

318520

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 53525, IRAS 318520

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

Study design

Multicentre prospective observational study

Primary study design

Observational

Secondary study design

Diagnostic accuracy study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/sono-breech/_recache

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2023

Completion date

30/06/2026

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

Age group

Adult

Sex

Female

Target number of participants

9648

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

01/02/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Queen Charlotte's and Chelsea Hospital - Imperial College Healthcare NHS Trust

United Kingdom

W12 0HS

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

Study participating centre
Ipswich - East Suffolk and North Essex NHS Foundation Trust
United Kingdom
IP4 5PD

Study participating centre
West Suffolk Hospital - West Suffolk NHS Foundation Trust
United Kingdom
IP33 2QZ

Study participating centre
East Surrey Hospital - Surrey and Sussex Healthcare NHS Trust
United Kingdom
RH1 5RH

Study participating centre
Northwick Park Hospital - London North West University Healthcare NHS Trust
United Kingdom
HA1 3UJ

Study participating centre
James Cook University Hospital - South Tees Hospitals NHS Foundation Trust
United Kingdom
TS4 3BW

Study participating centre
Lincoln County Hospital & Pilgrim Hospital Boston - United Lincolnshire Hospitals NHS Trust
United Kingdom
LN2 5QY

Study participating centre

St George's Hospital - St George's University Hospitals Foundation Trust
United Kingdom
SW17 0QT

Study participating centre
City Hospital - Sandwell and West Birmingham Hospitals NHS Trust
United Kingdom
B71 4HJ

Study participating centre
Birmingham Women's and Children's Foundation Trust
United Kingdom
B4 6NH

Study participating centre
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United Kingdom
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Study participating centre
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Sponsor type
University/education

Website
<http://www.imperial.ac.uk/>

ROR
<https://ror.org/041kmwe10>

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The project includes an integral three-step plan:

Step one: Participant-facing, targeting those service users and staff involved in the study across all sites to ensure inclusivity and transparency. Dissemination of plain English progress reports via a regular newsletter emailed directly to those involved, while informatic summaries of the newsletter will be displayed across the participating Trusts on staff and service user notice boards.

Step two: a web and social media-based plan will focus on wider dissemination of the research progress and findings with a dedicated study website with a Twitter and Instagram feed curated by the Cardiff Trials Unit. The study's PPIE collaborators, which include members from a range of service user action groups, will take an active role to ensure that families and maternity service users across the country maximise the study's potential impact.

Step three: Clinical and academic conference presentations and submissions to high-impact clinical journals which this team is well placed to undertake.

Intention to publish date

30/06/2027

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date