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Can pocket-sized ultrasound devices be used safely and acceptably in routine pregnancy care?

Submission date
27/08/2025

Recruitment status
Recruiting

Registration date
28/08/2025

Overall study status
Ongoing

Last Edited
28/08/2025

Condition category
Pregnancy and Childbirth

[X] 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
Ultrasound scans are an important part of pregnancy care and are used to check the baby's growth and wellbeing. Standard ultrasound machines are large, costly, and need specialist staff. New hand-held ultrasound devices are smaller, cheaper, and easier to use, but we do not yet know if they are reliable enough or acceptable to pregnant people. This study aims to find out whether it is practical to run a larger trial in the future and whether people are happy to have this type of scan.

Who can participate?
Pregnant people aged 18 years or over who are attending Liverpool Women's Hospital for routine care, such as monitoring for diabetes, small or suspected small babies, or reduced fetal movements.

What does the study involve?
Participants will be asked to have an additional ultrasound scan using a hand-held device during their routine appointment, alongside the standard scan already planned. Afterwards, they will complete a short questionnaire about their experience.

What are the possible benefits and risks of participating?
Participants will be offered a scan picture of their baby, if position allows. Their involvement may help improve pregnancy care in the future. There are no known risks from the extra scan, as ultrasound is considered safe in pregnancy.

Where is the study run from?
The study is being run at Liverpool Women's Hospital NHS Foundation Trust, supported by the University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
January 2025 to August 2026

Who is funding the study?
The study is supported in kind by Liverpool Women’s Hospital, which is providing the salary of the principal investigator. No external grant funding has been received.

Who is the main contact?
Dr Kelsey Lennox, kelsey.lennox@nhs.net

Study website
https://liverpoolhealthpartners.org.uk/jro/research-sponsorship/

Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
351278

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UoL001929

Study information

Scientific Title
Routine Use of Focussed UltraSound in Antenatal Fetal Imaging (RUFUS-AFI)

Acronym
RUFUS-AFI

Study objectives
This study aims to assess whether small hand-held ultrasound devices can be reliably and acceptably used alongside standard ultrasound scans in pregnancy care. The main objectives are to:
1. Explore whether it is feasible to run a larger trial comparing hand-held ultrasound with standard ultrasound in antenatal care.
2. Assess how acceptable hand-held ultrasound is to pregnant people.
3. Test whether the measurements obtained from hand-held ultrasound are reliable compared with standard scans.
4. Identify any practical issues, such as time taken or ease of use, that might affect future studies.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 22/08/2025, Fulham Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8340; Fulham.rec@hra.nhs.uk), ref: 25/PR/0942

Study design
Single-centre observational feasibility study with mixed quantitative and qualitative methods

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
https://docs.google.com/document/d/1Lbzel2O7uIN7dzH5g9ubK2b7PqnRVp-C/edit?usp=drive_link&ouid=103570073733126232184&rtpof=true&sd=true

Health condition(s) or problem(s) studied
Antenatal care in pregnancy, including people with diabetes, suspected small-for-gestational-age (SGA) babies, or reduced fetal movements

Interventions
Use of a hand-held point-of-care ultrasound device alongside routine standard ultrasound in pregnancy care.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vscan Air

Primary outcome measure
1. Feasibility and acceptability of using hand-held ultrasound in pregnancy, measured throughout the study period (up to 24 months). Specific indicators:
1.1. Recruitment rate (number and proportion of eligible participants recruited, at baseline)
1.2. Questionnaire completion rate (measured at the end of each participant's study involvement, at baseline)

1.3. Willingness to undergo future hand-held scans (reported immediately after the scan via questionnaire, at baseline)
1.4. Number of unblinding episodes (recorded prospectively during scanning session, at baseline)

Secondary outcome measures
1. Reliability of fetal biometry (head circumference, abdominal circumference, femur length, estimated fetal weight), assessed at the participant's study scan (at baseline), using intraclass correlation coefficients (ICC) and Bland–Altman plots.
2. Reliability of amniotic fluid volume and presentation recorded at the study scan (at baseline), using Kappa statistics.
3. Efficiency of scanning, measured as time taken (minutes) to complete hand-held ultrasound, recorded during each participant's study scan (at baseline).
4. Feasibility of measurement, recorded at the study scan (at baseline) as the proportion of participants in whom full biometric assessment could not be completed with the hand-held device.
5. Acceptability to participants, measured immediately after the scan (at baseline) by questionnaire responses on satisfaction and willingness to undergo future scans.

Overall study start date
28/01/2025

Completion date
31/08/2026

Eligibility

Key inclusion criteria
Pregnant patients attending Liverpool Women's Hospital for one or more of the following indications:
1. Routine assessment of the fetus due to maternal diabetes
2. Routine assessment of SGA fetus
3. Assessment of suspected SGA fetus on symphysis-fundal height measurement (SFH)
4. Reduced fetal movements
5. Able and willing to provide informed written consent for participation in the study
6. Aged 18 years or above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
180

Key exclusion criteria
1. Inability to provide informed consent
2. Patients who have an abnormal CTG necessitating urgent delivery, or in established preterm labour

Date of first enrolment
29/08/2025

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Women's NHS Foundation Trust
Liverpool Womens Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
University of Liverpool

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Sponsor type
University/education

Website
http://www.liv.ac.uk/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Liverpool Women's NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
28/02/2027

Individual participant data (IPD) sharing plan
Will IPD be shared?
Yes, but only fully anonymised data.

What type of data will be shared?
Anonymised quantitative data from ultrasound scans (fetal biometry, presentation, placentation, viability), basic maternal characteristics relevant to scan feasibility (e.g. BMI, smoking status, diabetes, hypertensive disease, fibroid uterus, generalised categories of medical history), and questionnaire responses on acceptability. No ultrasound images, identifiable information, or consent forms will be shared.

When will the data become available and for how long?
Anonymised datasets will be made available after study completion, once data are cleaned, locked, and published (anticipated 2027). Data will be retained and accessible for a minimum of 10 years, in line with University of Liverpool and Sponsor policy.

Where will the data be available?
Data will be deposited in the University of Liverpool Data Catalogue (DataCat), with a DOI assigned, and may also be made available as supplementary material to publications.

Access criteria and with whom will data be shared?
Data will be openly available under a Creative Commons Attribution (CC-BY) licence, allowing reuse with appropriate citation. Researchers and clinicians may use the data for secondary analyses relating to ultrasound in pregnancy.

How will data be anonymised?
All identifiers (name, date of birth, hospital/NHS numbers) will be removed. Maternal health conditions will be recorded only in broad categories to avoid rare disease identification. Ultrasound images will be deleted at study closure and not shared.

Ethical/legal considerations
Participants provide informed consent that anonymised data may be shared for future research. Data management follows GDPR and University of Liverpool data governance policies. Pseudonymised and identifiable data will remain confidential and stored securely for 10 years, after which they will be destroyed.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	08/08/2025	28/08/2025	No	Yes
Protocol file	version 1.1	08/08/2025	28/08/2025	No	No