

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

<b>Submission date</b> 27/08/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/08/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/01/2026	<b>Condition category</b> 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

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, planned caesarean birth, 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, or prior to planned caesarean birth. 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?

October 2025 to March 2027

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

## Contact information

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Public, Scientific, Principal investigator

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

351278

### **Protocol serial number**

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

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Antenatal care in pregnancy, including people with diabetes, suspected small-for-gestational-age (SGA) babies, planned caesarean birth, or reduced fetal movements. Healthcare professionals in Maternity settings

**Interventions**

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

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Vscan Air

**Primary outcome(s)**

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)

**Key secondary outcome(s)**

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.

**Completion date**

10/03/2027

# 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

Added 27/01/2026:

UK healthcare professionals working in maternity care, or worked in maternity care <5 years ago

## Participant type(s)

Health professional, Patient, Resident, Service user

## Healthy volunteers allowed

No

## Age group

Mixed

## Lower age limit

18 years

## Upper age limit

100 years

## Sex

Female

## Total final enrolment

0

## Key exclusion criteria

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

Added 27/01/2026:

3. Healthcare professionals retired or out of clinical practice >5 years

## Date of first enrolment

10/10/2025

## Date of final enrolment

10/10/2026

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**Liverpool Women's NHS Foundation Trust**

Liverpool Womens Hospital

Crown Street

Liverpool

England

L8 7SS

# Sponsor information

## Organisation

University of Liverpool

## 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

## 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?
<a href="#">Participant information sheet</a>	version 1.1	08/08/2025	28/08/2025	No	Yes
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Participant information sheet</a>	version 3.1	15/01/2026	27/01/2026	No	Yes
<a href="#">Participant information sheet</a>	version 1.0	17/11/2025	27/01/2026	No	Yes

<a href="#">Protocol file</a>	version 1.1	08/08/2025	28/08/2025	No	No
<a href="#">Protocol file</a>	version 3.0	11/11/2025	27/01/2026	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes