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Fetal ultrasound randomised trial of AI-assisted workflow for anomaly detection with health economic assessment

Submission date
30/07/2025

Recruitment status
Recruiting

Registration date
19/02/2026

Overall study status
Ongoing

Last Edited
05/06/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
This study is exploring whether new computer-based tools can improve pregnancy ultrasound scans. In the UK, pregnant women are usually offered a detailed scan halfway through pregnancy to check how their baby is developing. However, some serious health conditions can be missed. Researchers have developed artificial intelligence (AI) tools that can help spot problems during the scan and support expert review afterwards. The aim is to find out if using both tools together helps detect more problems early and makes clinics run more efficiently.

Who can participate?
Around 9,500 pregnant people will be invited to take part in the study. Participation is entirely voluntary.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive the usual scan, while the other group will have a scan supported by AI and reviewed by an expert. Some participants may also be asked to complete a short survey or take part in an interview to share their views.

What are the possible benefits and risks of participating?
Taking part could help improve how pregnancy scans are done in the future and may lead to earlier detection of health problems in babies. There are no known risks beyond those of a standard scan. Participation will not affect the care participants receive.

Where is the study run from?
King’s College London (UK)

When is the study starting and how long is it expected to run for?
July 2025 to June 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Professor Reza Razavi, reza.razavi@kcl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
355136

Central Portfolio Management System (CPMS)
71420

Protocol serial number
R&D 1388

Study information

Scientific Title
Fetal ultrasound randomised trial of AI-assisted workflow for anomaly detection with health economic assessment

Acronym
FRAIYA

Study objectives

Current study objectives as of 05/06/2026:
Gather stakeholder opinions on the acceptability of the AI-supported technology, and how this can be integrated into current clinical workflows. Also evaluate the usability of AI disease detection algorithms in routine clinical workflow.

Primary Outcomes:
1. Scan duration
2. Detection rate of congenital anomalies

Secondary Outcomes:
1. Qualitative assessment of user and patient acceptability
2. The accuracy of AI disease detection models in helping with detection rate of congenital anomalies
3. Diagnostic accuracy metrics (true positives, false positives, true negatives, false negatives, sensitivity, specificity, positive predictive value, and negative predictive value)
4. Referral to specialist fetal medicine or fetal cardiologist
5. Local follow-up scanning (including recalls for repeat scanning) after the 20-week scan
6. Screen-positive rates
7. Positive predictive value of referral

Previous study objectives:
Can an AI-enabled workflow for ultrasound screening of prenatal abnormalities, including second review, improve detection rates in a cost-effective way?

Primary Outcomes:
1. Scan duration
2. Detection rate of congenital anomalies

Secondary Outcomes:
3. Qualitative assessment of user and patient acceptability

At the end of the study, we'll know whether this technology helps detect serious conditions earlier, whether it's acceptable to patients and staff, and whether it could be affordable for the NHS. We'll share our findings through public summaries, press releases, and scientific conferences.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/12/2025, Yorkshire & The Humber - Leeds East Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; leedseast.rec@hra.nhs.uk), ref: 25/YH/0243

Primary study design
Interventional

Study design
Balanced two-arm explanatory randomized controlled trial with parallel process evaluation

Study type(s)

Screening

Health condition(s) or problem(s) studied
Ultrasound screening of prenatal abnormalities

Interventions
Pregnant women will be recruited to participate in the trial at the time of their mid-trimester ultrasound anomaly scan. Each participant will be randomised (1 to 1) to have the scan either with AI assistance (FraiyaScan), or in standard unassisted fashion. Those who have been randomised to AI assistance will also have an AI-assistance secondary review of the scan (FraiyaDetect). The scan duration and detection rates of congenital anomalies between the two scanning methods will be compared.

A parallel process evaluation will employ a convergent parallel design based on survey and interview data from service users (main trial service users) and the healthcare workforce (end user stakeholders).

Interventional and control arms are both going to last 26 weeks from the initial participation (20 week antenatal scan) to final question about the newborn outcome at 6 weeks of age. Randomisation (1-1) is via a digital application provided by the clinical trials unit (KCL CTU) that runs on the tablet attached to the ultrasound machine.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FraiyaScan, FraiyaDetect

Primary outcome(s)
Current primary outcomes as of 05/06/2026:
1. Scan duration: Time (minutes) to complete 20-week anomaly scan, measured using ultrasound machine timestamps/scan logs at 20-week scan
2. Detection rate of congenital anomalies: Proportion identified on ultrasound, measured against postnatal diagnosis and/or specialist confirmation at 20-week scan and postnatal follow-up

Previous primary outcomes:
1. Scan time in minutes (collected by the computer connected to the ultrasound machine that is recording the examination)
2. Correct diagnosis of a congenital abnormality in the newborn (confirmed by the follow-up call at 6 weeks to parents by a member of the research team and recorded on to the eCRF). The initial diagnosis of an abnormality if present is recorded at the time of the scan on the eCRF by the scanning sonographer

Key secondary outcome(s)
Added 05/06/2026:
1. User and patient acceptability: Acceptability scores and qualitative feedback, measured using questionnaires/interviews at 20-week scan

2. Accuracy of AI-assisted anomaly detection: Proportion detected with AI vs standard assessment, measured against postnatal diagnosis and/or specialist confirmation at 20-week scan and postnatal follow-up
3. Diagnostic accuracy metrics: calculated from ultrasound findings vs reference standard (postnatal diagnosis/specialist confirmation) at 20-week scan and postnatal follow-up
4. Referral to specialist services: Proportion referred to fetal medicine/cardiology, measured from clinical records at 20-week scan and antenatal follow-up
5. Follow-up scanning (recalls): Proportion requiring additional scans post 20-week scan, measured from imaging records during pregnancy
6. Screen-positive rate: Proportion of scans indicating suspected anomalies requiring further assessment, measured from ultrasound reports at 20-week scan
7. Positive predictive value of referral: Proportion of referred cases confirmed as anomalies, measured against specialist diagnosis and/or postnatal outcomes at referral and postnatal follow-up

Completion date
30/06/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/06/2026:
For pregnant participants:
1. Booked for routine NHS mid-trimester anatomy ultrasound scan
2. Viable singleton pregnancy
3. Appointment booked ina participatingultrasound room

For healthcare workforce professionals:
1. NHS staff members at participating hospital sites and staff members at industry partner

Previous inclusion criteria:
1. Pregnant
2. All cases who are due for a routine mid-trimester (18-22 week) antenatal scan

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex

Female

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 05/06/2026:
For pregnant participants:
1. Under 18years of age
2. Multiple pregnancy
3. Confirmed presence of fetal structural anomalies
4. Confirmed presence of fetal chromosomal/genetic anomaly
5. High-risk pregnancy(e.g., under care of fetal medicine/fetal cardiology)
6. Insufficient English language skills to provide informed consent (even with available translation materials)

For healthcare workforce professionals:
1. Staff groups or professionals not involved in ultrasound services; IT or network security; procurement; service or industry managers.

Previous exclusion criteria:
1. Any identified structural abnormality
2. Any genetic or chromosomal abnormality identified
3. Participant withdrawal
4. Refusal of consent
5. Insufficient English language skills to provide informed consent
6. Multiple pregnancies

Date of first enrolment
08/04/2026

Date of final enrolment
05/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guys and St Thomas's NHS Foundation Trust
Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
Lewisham and Greenwitch NHS Trust
Lewisham High St
London
England
SE13 6LH

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

Study participating centre
William Harvey Hospital
Kennington Road
Willesborough
Ashford
England
TN24 0LZ

Study participating centre
Queen Elizabeth the Queen Mother Hospital
St. Peters Road
Margate
England
CT9 4AN

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website		11/11/2025	11/11/2025	Yes	Yes