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

Submission date
30/07/2025

Registration date
19/02/2026

Last Edited
19/02/2026

Recruitment status
Recruiting

Overall study status
Ongoing

Condition category
Pregnancy and Childbirth

[_] 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

Central Portfolio Management System (CPMS)
71420

Integrated Research Application System (IRAS)
355136

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

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)
notYetSubmitted

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

Primary study design
Interventional

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).

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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)
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))
There are no secondary outcome measures

Completion date
30/06/2027

Eligibility

Key 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
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex

Female

Total final enrolment

0

Key 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

01/10/2025

Date of final enrolment

01/10/2026

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
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

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	Study website	11/11/2025	11/11/2025	No	Yes