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Artificial intelligence to help improve fetal ultrasound scanning

Submission date	Recruitment status	[X] Prospectively registered
07/06/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2024	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims

All pregnant women in the UK are offered an ultrasound scan at roughly halfway through their pregnancy to try and identify certain health issues in the baby. These scans are performed because babies are more likely to survive after birth if health issues are identified before birth, compared to after birth. This is because they can be treated properly as soon as they are born, rather than after a delay. Unfortunately, not all health issues are identified before birth. This is because ultrasound scans are difficult to perform and interpret, and there is a shortage of people able to do these scans. Some areas of the UK are much worse at diagnosing these babies than others. The aim of this study is to find out if AI can help the people doing these scans, by assisting them and telling them when the baby has a health issue. The research group has already used computers to help recognise different parts of the baby and to automatically measure the baby's size. They would like to develop these computer systems to also tell which babies have health issues.

Who can participate?

1. Pregnant women whose fetus is either thought to have no health problems, or whose fetus has been identified as having a health problem.
2. Sonographers who regularly perform fetal anomaly ultrasound scans as part of their usual work.

What does the study involve?

Each pregnant woman will be scanned twice, once in the usual way and once using artificial intelligence assistance. The sonographers will be randomised to perform scans using one of these methods, and will each perform three scans.

What are the possible benefits and risks of participating?

This study places only a relatively small burden on participants, involving two extra ultrasound scans on a single day for the pregnant women, and the performance of three scans in a single day for the sonographers. Ultrasound in pregnancy has been shown to be safe and is in mainstream clinical use. The use of AI will not affect the safety of the scan. The main risk to pregnant women would be the detection of a fetal medical problem that had previously been overlooked, and there will be an 'incidental findings' procedure in place to manage these

appropriately. Ultrasound scanning can be uncomfortable during pregnancy, and the scans will be stopped immediately if the participant requests. In addition, the pregnant participant will be able to undergo the scan in whatever position they find most comfortable. The researchers will contact the women after delivery for those included as normal controls, to ensure that the antenatal diagnosis of a normal fetal heart was correct. This could be upsetting if the baby had become unwell or died during delivery or in the newborn period.
There will be no direct benefit to either pregnant participants or volunteer sonographers for taking part.

Where is the study run from?
Guy's and St Thomas' Hospital, King's College London (UK)

When is the study starting and how long is it expected to run for?
December 2019 to October 2023

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

Who is the main contact?
Dr Thomas Day
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

292223

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 52243, IRAS 292223

Study information

Scientific Title
PROMETHEUS: Prospective tRial of Machine lEarning To Help fEtal Ultrasound Scanning

Acronym
PROMETHEUS

Study objectives
Artificial intelligence assistance will improve the detection rate of fetal anomalies compared to standard manual scanning, and will result in a faster scan with a lower cognitive load.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/04/2022, London Dulwich REC (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048089; dulwich.rec@hra.nhs.uk), ref: 22/LO/0163

Study design
Randomized; Interventional; Design type: Screening, Diagnosis, Device, Imaging

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Fetal ultrasound scanning

Interventions
1. Ultrasound scan using artificial intelligence assistance
2. Ultrasound scan without using artificial intelligence assistance

Each pregnant woman will be scanned twice, once in the usual way and once using artificial intelligence assistance. The sonographers will be randomised to perform scans using one of these methods, and will each perform three scans.

Intervention Type
Other

Primary outcome(s)
Detection rates of fetal anomaly between the two groups, assessed by written report by the sonographer, at baseline

Key secondary outcome(s))
1. Time taken to complete ultrasound scan and written report, measured using a timekeeping device, at baseline
2. Cognitive load of sonographer after each scan, measured by NASA TLX scale, at baseline

Completion date
02/10/2023

Eligibility

Key inclusion criteria
1. Cases: pregnant women with a fetus diagnosed with structural malformation between 12+0 and 27+6 weeks' gestation.
2. Controls: pregnant women with a fetus shown not to have a structural malformation, between 18+0 and 27+6 weeks' gestation.
3. Sonographers: professional staff who regularly and routinely undertake fetal anomaly screening ultrasound scans

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
80

Key exclusion criteria
For pregnant participants (cases/controls):
1. Any identified fetal extracardiac structural abnormality
2. Any fetal genetic or chromosomal abnormality
3. Participant withdrawal
4. Refusal of consent
5. Insufficient English language skills to provide informed consent

For sonographers:
1. Any previous involvement in the iFIND research project
2. Previous involvement in the research leading up to this trial

Date of first enrolment
15/11/2022

Date of final enrolment
02/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Thomas' Hospital
St. Thomas's Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AB

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: NIHR301448

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 09/01/2023:
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

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

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		25/05/2024	31/05/2024	No	No