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Intelligent Fetal Imaging and Diagnosis (iFIND)

Submission date
19/03/2015

Recruitment status
Suspended

Registration date
30/03/2015

Overall study status
Completed

Last Edited
10/04/2024

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
There is a need to improve the accuracy of the 18-20 week fetal ultrasound scan. This is because current technologies and screening methods do not pick up all of the abnormalities that could be detected. It is important to be able to spot any potential problems with the fetus (baby) before he/she is born. Making a diagnosis prenatally (before a baby is born) allows the expectant parents to make informed choices about whether or not to continue with the pregnancy. It can also improve a baby's prospects by allowing a treatment plan to be produced from the moment the baby is born. We would like to improve ultrasound scanning so that in the future all babies have the best outcome possible.

Who can participate?
Adult women (at least 18) who are between 18-24 weeks pregnant.

What does the study involve?
Ultrasound data from the routine 20 week scan from willing participants are saved to use for research to help us improve ultrasound scanning in the future. The scan itself is performed exactly as usual but instead of only a selection of snapshots of the baby being recorded, as is usually the case, the data from the whole ultrasound recording from the scan is saved and retained for this research study. Participants choosing to take part in the second part of the study have additional ultrasound images of their baby performed. The data is used the data to teach our new imaging system the best way to capture high quality images. We would also like to collect as many images as we can to build a database of the baby's body which computer programmes can use to compare with new ultrasound images. In this way we hope to be able to automatically detect different fetal organs and diagnose whether or not they are developing normally. Most women taking part in the study will have their research ultrasound and MRI scan on the same day. If they prefer, it may be possible for them to have the research ultrasound scan and the MRI scan a few days apart from each other.

What are the possible benefits and risks of participating?
If the participant is just having the data from their routine 20 week scan recorded there are no direct benefits to them. However, in the future we hope that the information gained from the study will lead to better antenatal diagnosis of fetal abnormalities and be used in all antenatal clinics nationally. Participants taking part in the additional research scans will be given a copy of the MRI scan of their baby, including a short video (cine) of their baby, and may also be given a

3D ultrasound picture. The fetal ultrasound has no perceived risks. We have thoroughly investigated all known potential risks to the baby and to the best of our knowledge and that of the medical community there are no additional risks to the baby or long-term effects of having the MRI scan. In addition, the MRI scan is not believed to have hazards associated with it when operated within National Radiological Protection Board Guidelines (which we do).

Where is the study run from?
The research is organised by and Kings College London and Guys and St Thomas' NHS Foundation Trust. The study is run from St Thomas' Hospital in London

When is the study starting and how long is it expected to run for?
March 2014 to April 2023

Who is funding the study?
The study is funded by the charity the Wellcome Trust and the Engineering and Physical Sciences Research Council.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A computer-guided Imaging System for prenatal screening and comprehensive diagnosis of fetal abnormalities

Study objectives
Prenatal diagnosis of congenital abnormalities has become increasingly important. Making a diagnosis during fetal life permits expectant parents to make informed choices about the continuation of pregnancy. Prenatal diagnosis of some abnormalities can also improve fetal prognosis by allowing a treatment plan to be produced. This will enable access to specialist units and appropriate treatments from birth, rather than having a baby born that is severely ill and does not have a clear diagnosis or treatment plan.
Currently, screening for fetal abnormalities by ultrasound takes place at 12 weeks and 18-20 weeks. The 12-week scan is focused on looking for markers of chromosomal abnormality rather than structural abnormalities, because the fetus is small and anatomical structures are not fully developed. Although anatomical structures are developed at the 18-20 week scan, it can sometimes be difficult to obtain clear images, for instance if the fetus is in an unfavourable position.
Ultrasound is a powerful tool in fetal imaging. It is inexpensive, safe and portable, and images are acquired in real-time. Ultrasound passes sound waves into the body to create pictures from their reflections. It is commonly used to see if babies in the womb are healthy. Although every pregnant mother in the country has a scan at around 20 weeks, many of the babies who have problems are not picked up on these ultrasound scans. This is because scanning requires significant expertise which is difficult to have present in every hospital. We are proposing new technologies that allow scanning to be carried out not just with one probe (the device which takes the ultrasound picture) but up to four probes that can be used at the same time, and which move automatically to the right place to get the best pictures. This will mean we get a detailed picture of the whole baby which can then be analysed in an automatic way using advanced computer technologies to ensure we do not miss babies with potential problems. This should mean a high quality scanning service across the country and fewer babies who have major problems will be missed.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee London – Riverside, 10/12/2014, refs: 14/LO/1805 and 14/LO/1806.

Study design
Observational, cross-sectional, single-centre study.

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Our aim is to improve prenatal diagnosis rates for fetal abnormalities

Interventions
We will gather ultrasound and some MRI data from pregnant ladies at the time of their anomaly scan (18-24 week's gestation) and use this to develop computer aided diagnostics, build fetal atlases and develop a multi-transducer ultrasound system to automate fetal anomaly detection and improve the rates of their diagnosis.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The data from up to 20,000 routine anomaly scans performed at 18-21 week's gestation will be collected.

Key secondary outcome(s))
Ultrasound and MRI imaging data will be used in combination with information on image labelling and image acquisition (transducer position and pressure sensing) obtained at 20-25 week's gestation.

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Pregnancy at 18+0 to 24+6 weeks at time of scan
2. 18 years of age and over
3. Competent to read information sheet and understand the purpose of the study and what it would entail.
4. Competent to read information sheet and understand the purpose of the study and what it would entail. Where English is poor an interpreter will be used.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Inability to understand study information given in written form and explained verbally
2. Contraindication to MRI e.g. metallic implant or foreign body or pacemaker
3. Severe obesity as the mother may not fit in the magnet
4. Severe claustrophobia (unusual, but patient asked if can go in an elevator as a screen for severity of problem)

Date of first enrolment
27/02/2015

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Guys and St Thomas' NHS Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Research council

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
EPSRC Engineering & Physical Sciences Research Council, UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, The Engineering and Physical Sciences Research Council (EPSRC), EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Other publications	Observer agreement and variability study	29/01/2018	10/04/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes