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How does breathing in extra oxygen during late pregnancy change fetal blood flow and can this be used to help babies with congenital heart defects?

Submission date
09/03/2020

Recruitment status
No longer recruiting

Registration date
01/04/2020

Overall study status
Completed

Last Edited
30/06/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The diagnosis of defects before birth allows for the planned provision of potentially life-saving postnatal care, and time for effective counselling of prospective parents. Some conditions, such as specific forms of congenital heart disease, can be extremely difficult to diagnose accurately in fetal life, making accurate planning and appropriate counselling extremely difficult.
The researchers are proposing using the fetal and maternal response to oxygen, delivered for a short period during an ultrasound or MRI scan, to help provide more detailed diagnostic information for mother and baby. Giving maternal oxygen is known to be safe, and has subtle but fully reservable effects on the placenta and the fetal circulation. If the placenta of the fetal circulation are not functioning normally, the response to oxygen will be different.
The researchers hope to improve our understanding of these changes, so that oxygen may be used to help improve the accuracy of diagnosis before birth. This simple bedside test then has the potential to be used by specialists around the country.

Who can participate?
Women aged 18 years or older with a pregnancy at 18 weeks or later at the time of participation.

What does the study involve?
Participants will have a 60-minute ultrasound scan and/or 60-minute MRI scan in addition to their usual treatment.

What are the possible benefits and risks of participating?
Benefits: There will be no direct benefit to research participants. However as the participants will be undergoing an MRI it is possible that this will detect a problem not evident on the ultrasound examination.
Risks: None. MRI is a routine and safe procedure.

Where is the study run from?
Guy's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2017 to May 2022

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr David Lloyd
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
213115

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 33666, IRAS 213115

Study information

Scientific Title
Maternal hyperoxygenation in diagnostic fetal imaging

Acronym

FIMOx

Study objectives
Maternal hyperoxygenation will have measurably different effects on the fetal circulation in the presence of certain forms of congenital heart disease or other fetal or placental pathologies

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/04/2017, London - South East REC (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 17/LO /0282

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Other obstetric conditions, not elsewhere classified

Interventions
The researchers plan to recruit 200 mothers with either healthy pregnancies, or known congenital or placental abnormalities which have been identified in their routine 20-week anomaly scan for additional scanning. These patients will be contacted initially by fetal medicine or fetal cardiology specialists at the time of their anomaly scan and be given information about the study including the patient information sheet. They will then have time to consider participation in the study. If they have agreed to participate they will be booked to come for an ultrasound scan and a fetal MRI study at their convenience, during which oxygen will be administered for a short period of time.

The mothers will be brought to St Thomas' Hospital to a dedicated room for their research scans. Signed consent will be taken. The ultrasound appointment will consist of up to 60 minutes of imaging performed by a trained fetal sonographer to acquire new images including both 2D and 3D images as well as Doppler blood flow data. Electrocardiographic (ECG) stickers may be placed on the maternal abdomen during the ultrasound to permit acquisition and analysis of advanced

ultrasound data. This will cause no pain or discomfort and these will be simply removed at the end of the examination.

Participants will also have a fetal MRI scan lasting up to 60 minutes each. Patients will fill in an MRI safety questionnaire to ensure there are no exclusion criteria for entering a magnetic field. The actual time scanning the fetus will be up to 60 minutes plus the time required to comfortably position the mother on the table and preparing them for the scanning with the appropriate hearing protection and MRI coils. If required, a break of up to 15 minutes may be taken in the middle of the scan to ensure patient comfort. Imaging of the fetus will then be performed.

For some women, the researchers may ask if they would be willing to re-attend for up to one further ultrasound and/or MRI scan later in the pregnancy, provided they are willing to do and continue to fulfil the relevant inclusion and exclusion criteria.

Maternal information and data recorded in databases and medical notes part of standard care will also be collected for the development of our research.

The researchers will collect outcome data from each participant, up to a period of six months after the expected date of delivery for the pregnancy. In the majority of cases, the researchers expect to be able to retrospectively obtain this data from participants' medical records with their consent, obtained at the time of enrolment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ultrasound, MRI

Primary outcome measure
Fetal blood flow in the third trimester of normal pregnancies and those associated with fetal or placental pathologies measured by Ultrasound and Magnetic Resonance Imaging at baseline and with additional temporary oxygen supplementation

Secondary outcome measures
1. Placental volume measured by Magnetic Resonance Imaging at scan timepoint
2. Fetal weight measured by Magnetic Resonance Imaging at scan timepoint
3. Brain tissue volumes measured by Magnetic Resonance Imaging at scan timepoint
4. Changes to placental oxygen environment of normal pregnancies and those associated with fetal or placental pathologies measured by blood oxygen level dependent magnetic resonance imaging at baseline and with additional temporary oxygen supplementation
5. Pregnancy demographic and biometric outcome data, including but not limited to congenital heart diagnosis at birth, gestational age at birth, birth weight, head circumference

Overall study start date
01/06/2017

Completion date

31/05/2022

Eligibility

Key inclusion criteria
1. Women with a pregnancy at 18 weeks or later at the time of scan
2. 18 years of age and over
3. Can read the information sheet and understand the purpose of the study and what it would entail

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria
All groups
1. Maternal weight > 125kg
2. Maternal claustrophobia
3. Patients in the first trimester of pregnancy
4. Use of any of the following medication: adriamycine, bleomycine, actinomycine, menadion, chlorpromazine, thiordiazine, chloroquine
5. Severe maternal respiratory pathology
6. Unable to give informed consent
7. Contra-indication to MRI

Healthy controls
8. Fetal growth restriction
9. Fetal congenital anomaly
10. Maternal placental insufficiency

Date of first enrolment
11/09/2017

Date of final enrolment
31/05/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Guy’s Hospital
Guy’s & St Thomas’ NHS Foundation Trust
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Wellcome Trust/EPSRC Centre for Medical Engineering [WT203148/Z/16/Z]

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality.

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