Feasibility of performing Blood Oxygen Level-Dependent MRI of the placenta

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28029

Source
NTR

Brief title
TBA

Health condition

Women with uncomplicated, singleton pregnancies between 28 and 34 weeks of gestational age.

Sponsors and support

Primary sponsor: Erasmus MC Department of Obstetrics and Gynaecology
Source(s) of monetary or material Support: Stichting Groenendijk Clemens

Intervention

Outcome measures

Primary outcome

The percentage of participants with successful BOLD MRI. The study will be considered feasible when at least 78% of participants have an analysable BOLD signal, defined as a

change in signal intensity with a $p<0.05$ between different stages of oxygenation.

Secondary outcome

None

Study description

Background summary

The placenta is an essential regulatory organ that provides the fetus with nutrients and oxygen. Optimal placenta function is crucial for fetal health and subsequent neonatal outcome. Insufficient development of the placenta can lead to serious pregnancy complications, such as fetal growth restriction (FGR), increasing the risk of short and long term health consequences. Early prenatal detection of high risk fetuses and intensive monitoring could minimize these risks.
In the current clinical setting the gold standard for the detection and monitoring of FGR is ultrasound biometry combined with Doppler parameters. However, ultrasound examination predicts fetal outcome through an indirect estimate of placental function, and has limited value for identifying impaired placental development.
Functional Magnetic Resonance Imaging (fMRI) is a promising, non-invasive technique for a more direct assessment of placental function. Blood Oxygen Level-Dependent (BOLD) MRI is an fMRI technique that measures changes in tissue oxygenation during different states of oxygenation. By analysing these changes, placental function can be assessed. This technique could present an additional diagnostic tool which identifies fetuses at risk for FGR. Additionally, this technique could differentiate between FGR and constitutionally small fetuses.

Study objective

The primary objective is feasibility of performing BOLD MRI of the placenta in our centre.

Study design

01-09-2019

Intervention

Not applicable (Observational study with invasive measurement).

Contacts

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Eligibility criteria

Inclusion criteria

- Singleton, uncomplicated pregnancy between 28 and 34 weeks of gestation
- Understanding of Dutch in speaking and reading
- Signed informed consent (willingness to participate in the study)
- Minimal age of 18 years

Exclusion criteria

- Unknown or uncertain gestational age
- Congenital anomalies detected by ultrasound
- Multiple pregnancy
- (Gestational) diabetes
- Preeclampsia or fetal growth restriction
- Claustrophobia (because of the necessity to be in an MRI chamber)
- Inability to give informed consent (e.g. mentally impaired)
- Women with a pacemaker, cochlear implants, neurostimulator or subcutaneous insulin pump (contraindications for MRI).
- Not willing to be informed about incidental findings following the performance of the MRI

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	14
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-07-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48878
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7900
CCMO	NL65570.000.18
OMON	NL-OMON48878

Study results