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

Published: 16-05-2019
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The primary objective is feasibility of performing BOLD MRI of the placenta in our centre.

Ethical review	Approved WMO
Status	Completed
Health condition type	Placental, amniotic and cavity disorders (excl haemorrhages)
Study type	Observational invasive

Summary

ID

NL-OMON48878

Source
ToetsingOnline

Brief title
Placenta and BOLD MRI

Condition

- Placental, amniotic and cavity disorders (excl haemorrhages)

Synonym
Placental function, placental oxygenation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: BOLD MRI, Placental function, Pregnancy between 28 and 34 weeks of gestation

Outcome measures

Primary outcome

The percentage of participants with successful BOLD MRI.

Secondary outcome

Not applicable.

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

Observational study with invasive measurement.

Intervention

Oxygen supply.

Study burden and risks

MRI is safe in pregnancy. No intravenous contrast agent will be used. No negative effects on fetal outcome have been described for short-term maternal oxygen therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-10-2019
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO Date:	16-05-2019
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-08-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28029
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65570.000.18
Other	NL7900
OMON	NL-OMON28029