Inter- and intra-observer variability in cerebroplacental ratio measurements in fetuses between 32 and 40 weeks of gestation.

Published: 16-07-2020
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To assess the inter- and intra-variability of MCA PI, UA PI, UtA PI and CPR between 32 and 40 weeks of gestation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON49138

Source
ToetsingOnline

Brief title
CPR inter- and intra-observer variability

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Doppler ultrasound; Cerebroplacental Ratio

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cerebroplacental Ratio, Variability

Outcome measures

Primary outcome

Inter- and intra-observer reproducibility of the MCA, UA, UtA pulsatility

indices (PI) and the CPR.

Secondary outcome

Correlation between gestational age and the inter- and intra-variability of

pulsatility indices (PI) of the MCA, UA, UtA and the CPR.

Study description

Background summary

Doppler ultrasound measurements are increasingly performed in clinical practice
to detect signs of fetal compromise and distinguish the healthy fetus from the
fetus at risk. These include the measurements of the pulsatility indices (PI)
of umbilical artery (UA) and the middle cerebral artery (MCA), as well as the
Cerebro Placental Ratio (CPR - which is calculated by dividing the MCA PI by
the UA PI). A low CPR - a sign of brainsparing - is indicative of placental
insufficiency and a marker of adverse pregnancy outcomes. Although currently
only used in clinical practice in the first en second trimester, the Doppler of
the uterine artery (UtA) is also gaining more and more attention as a third
trimester marker for placental function
However, the test characteristics have not been adequately studied yet.

Study objective

To assess the inter- and intra-variability of MCA PI, UA PI, UtA PI and CPR
between 32 and 40 weeks of gestation.

Study design

Prospective observational study.

Study burden and risks

Additional ultrasound measurements are performed just after the visit at the outpatient clinic. No extra hospital visit is required. These additional measurements take about 30 minutes. There are no risks or benefits associated with participation.

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 pregnancies between 32 and 40 weeks of gestation.

Exclusion criteria

- Maternal age <18 years
- Inability to give informed consent
- Chromosomal abnormalities or major congenital malformations (including SUA).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	16-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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: 25550
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL73766.018.20