

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

Published: 16-07-2020

Last updated: 04-06-2024

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 and 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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL73766.018.20