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

Published: 19-10-2020
Last updated: 15-05-2024

We hypothesize that the inter-observer variability of the CPR, MCA, UA and UtA measurement will be less than intra-observer variability due to normal biological variation of cardiovascular control.

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

Summary

ID

NL-OMON25550

Source
Nationaal Trial Register

Brief title
CPR observer variability

Condition

- Pregnancy, labour, delivery and postpartum conditions

Health condition

Pregnancy

Research involving
Fetus in utero

Sponsors and support

Primary sponsor: Amsterdam UMC, locatie AMC
Source(s) of monetary or material Support: AMC

Intervention

Outcome measures

Primary outcome

Inter- and intra-observer variability in Doppler ultrasound measurement of MCA, UA, UtA, CPR.

Secondary outcome

Secondary outcome includes the correlation between gestational age and inter- and intra-variability of the Doppler ultrasound measurements 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 the 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 is indicative of placental insufficiency and a marker of adverse 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 of these Doppler measurements in the third trimester of pregnancy have not been adequately studied yet. The aim of this study is to assess the inter- and intra-observer variability of Doppler ultrasound measurements in fetuses between 32 and 40 weeks of gestation, including the MCA, UA, UtA and CPR.

Study objective

We hypothesize that the inter-observer variability of the CPR, MCA, UA and UtA measurement will be less than intra-observer variability due to normal biological variation of cardiovascular control.

Study design

Primary outcome will be analysed after data completion of the 40 subjects. No follow up takes place.

Intervention

Not applicable

Contacts

Public
Amsterdam UMC, locatie AMC
Stefanie Damhuis

+31(0)205666199
Scientific
Amsterdam UMC, locatie AMC
Stefanie Damhuis

+31(0)205666199

Eligibility criteria

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

Inclusion criteria

Singleton pregnancies with gestational age between 32+0 and 40+0 weeks.

Exclusion criteria

- Maternal age <18 years - Inability to give informed consent - Multiple pregnancy - Abnormal fetal heart tracings - Major congenital malformations (including single umbilical artery) or chromosomal abnormalities

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	06-07-2020
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389

mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 49138
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8988
CCMO	NL73766.018.20
OMON	NL-OMON49138

Study results