Decidual vasculopathy in preeclampsia 3: Prediction and early detection

Published: 10-02-2012
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Storage of blood samples, placental material and ultrasonic measurements to be used in a future study the prediction of PE and DV.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Maternal complications of pregnancy
Study type	Observational invasive

Summary

ID

NL-OMON35148

Source
ToetsingOnline

Brief title
DEVAP 3

Condition

- Maternal complications of pregnancy

Synonym
HELLP syndrome, preeclampsia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: acute atherosis, decidual vasculopathy, prediction, preeclampsia

Outcome measures

Primary outcome

The aim of this study is storage of material and ultrasonic data. Subsequently, a larger study will be designed aimed to develope a tool for the prediction of preeclampsia and decidual vasculopathy. In this future study, the parameters will be levels of biomarkers and measurements of uterine artery flow.

Secondary outcome

Not applicable.

Study description

Background summary

Preeclampsia (PE) is a hypertensive disease of pregnancy of unknown etiology, defined by (the onset of) high blood pressure and proteinuria after 20 weeks of gestation, causing serious maternal and fetal morbidity. Decidual vasculopathy (DV) is a pathological finding of spiral arteries seen in PE. We previously showed an association of DV with disease severity and fetal outcome in PE. We concluded that PE with DV could represent a subclass of severe, early disease, with possibly a unique underlying disease process. The prediction of PE would enable closer monitoring and preventive interventions for high risk patients. Various biomarkers have been found to be associated with the development of PE, however, so far no single biomarker has been found to have a sufficient predictive power. We hypothesize that PE can be optimally predicted using a specific combination of biomakers. The prediction of PE with DV has not been studied. We hypothesize that DV will be associated with a specific set of biomarkers for the prediction of PE.

Study objective

Storage of blood samples, placental material and ultrasonic measurements to be used in a future study the prediction of PE and DV.

Study design

Blood samples will be drawn and stored. Additionally, uterine artery blood flow

will be measured ultrasonically. Measurements will take place in first and second trimester; peripartum and after onset of clinical disease in cases that develop preeclampsia. After delivery, placental material will be sampled and stored.

Study burden and risks

Pregnant women at 11-13 weeks GA, at 18-22 weeks GA, at time of development of PE (if applicable) and before delivery (for a maximum total of 5 times) will undergo blood sampling and ultrasonic examination of the uterine artery flow. 30-40 ml of blood will be drawn per sampling. After delivery, placental material will be sampled for histological analysis.

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

Adult pregnant women at 11-13 weeks gestational age

Exclusion criteria

Multiple pregnancies, cases with intra-uterine infections, cases with chromosomal abnormalities of the fetus (determined by karyotype, diagnostics will not be performed as part of this study)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO Date:	10-02-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL37724.091.11