

# The validation of putative prognostic factors for gestational complications in blood of pregnant women during the 2nd half of pregnancy.

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To collect maternal blood during the 2nd half of pregnancy, in combination with clinical data and data on pregnancy outcome.

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

## Summary

### ID

NL-OMON34648

### Source

ToetsingOnline

### Brief title

PANDA-antenatal

### Condition

- Pregnancy, labour, delivery and postpartum conditions

### Synonym

pregnancy complications

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W, subsidie is

aangevraagd

## Intervention

**Keyword:** hypertension, placenta, pregnancy, premature labour

## Outcome measures

### Primary outcome

The initial validation of factors with putative prognostic value for pregnancy complications that threaten health of mother and/or child.

### Secondary outcome

none

## Study description

### Background summary

About 25% of all pregnancies is complicated by gestational diseases that threaten well-being of mother and/or child. Severe preeclampsia (de novo hypertension and proteinuria after 20 weeks of gestation) and HELLP (acronym for Hemolysis, Elevated Liver enzymes and Low Platelets) syndrome are the main causes for pregnancy-related maternal mortality and morbidity. Intra-uterine growth retardation and premature delivery are the most prevalent additional causes of neonatal mortality and morbidity.

Recent investigations have identified a number of factors, mainly of placental origin, with a putative prognostic potential for pregnancy complications. The recently terminated PANDA study on placental profiles for gestational hypertensive disease has identified transcripts with increased expression in the placenta of women with pregnancy complications. These factors, that are present in the maternal circulation early in pregnancy, have a putative prognostic potential. Prognostic factors for obstetrical complications are important because this allows for more intensive monitoring of high risk patients and possibly also timely treatment in future. Before prospective studies on the prognostic value of these factors can be initiated, it first has to be established that they are able to differentiate between pregnant women with and without gestational disease.

### Study objective

To collect maternal blood during the 2nd half of pregnancy, in combination with clinical data and data on pregnancy outcome.

### **Study design**

This is an observational study. Pregnant women admitted to the AMC obstetrical ward will be asked to participate. The collected EDTA blood will be used to determine the levels of placenta specific RNA molecules and proteins.

### **Study burden and risks**

By means of a venipuncture 1 sample of 10 ml EDTA blood will be collected. This will be done maximally 3 times with a maximum frequency of 1 puncture per 7 days. Sampling will be combined with the taking of blood samples because of regular clinical care, as much as possible. The burden of a venipuncture is minimal. The risks are those associated with a venipuncture; a mild sore spot or a hematoma.

## **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

pregnant and admitted to the Obstetrics department during the 2nd half of pregnancy

### Exclusion criteria

HIV positive

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2010
Enrollment:	300
Type:	Actual

## Ethics review

Approved WMO

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

No registrations found.

### In other registers

Register	ID
CCMO	NL31931.018.10