# Decidual vasculopathy in preeclampsia 3A: Prediction and early detection (pilot study)

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a. To study whether a specific set of biomarkers is associated with PE with DVb. To study whether a specific set of biomarkers is predictive of PE with DV.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Maternal complications of pregnancy |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON35575

**Source**
ToetsingOnline

**Brief title**
DEVAP 3A

### Condition

- Maternal complications of pregnancy
- Vascular hypertensive disorders

**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

Levels of biomarkers and bilateral uterine artery flow in multiples of the

median (for details see page 12 of research protocol).

### Secondary outcome

Levels of biomarkers in multiples of the median (for details see page 12 of

research protocol)

# 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, which can cause 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.
PE has been associated with altered levels of various biomarkers, before and after onset of clinical disease. De association of DV with biomarkers is unknown. We hypothesize that PE with DV will be associated with a specific set of biomarkers, both before and after onset of PE.

### Study objective

a. To study whether a specific set of biomarkers is associated with PE with DV
b. To study whether a specific set of biomarkers is predictive of PE with DV.

### Study design

Prospective and retrospective case controlled pilot study. Cases with PE will be tested for blood biomakers associated with and predictive of PE. Also, bilateral uterine artery blood flow of cases will be measured ultrasonically. Placenta material will be analysed histologically. Lastly, blood biomarkers

will be retrospectively determined in samples from the first trimester of pregnancy. Cases with DV will be compared to those without the lesions.

### Study burden and risks

At time of admission and before delivery (for a maximum total of 5 times) patients will undergo blood sampling and ultrasonic examination of the bilateral uterine artery flow. 30-40 ml of blood will be drawn per sampling. After delivery, placental material will be sampled for histological analysis.

## Contacts

**Public**
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL
**Scientific**
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

Patients who are admitted at Radboud University Nijmegen Medical Centre with the diagnosis of preeclampsia.

### Exclusion criteria

Multiple pregnancies, signs of intra-uterine infection, chomosomal abnormalities of the fetus.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 03-05-2012 |
| Enrollment: | 70 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 03-02-2012 |
| 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 | NL38403.091.11 |