

# Ciculating endothelial cells in Preeclampsia

Published: 25-03-2008

Last updated: 17-08-2024

Primary objective: To demonstrate elevated numbers of CEC in clinically symptomatic patients with severe preeclampsia. Secondary objectives: - To analyze the relation of CEC levels with organ damage and dysfunction. - To analyze the relation of CEC...

<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-OMON32080

### Source

ToetsingOnline

### Brief title

CEC study

### Condition

- Pregnancy, labour, delivery and postpartum conditions

### Synonym

preeclampsia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

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

## Intervention

**Keyword:** CEC, Preeclampsia

## Outcome measures

### Primary outcome

Primary study parameter:

CEC levels in patients with severe preeclampsia

### Secondary outcome

Secondary study parameters

- To analyze the relation of CEC levels with organ damage and dysfunction.
- To analyze the relation of CEC levels with clinical parameters as bloodpressure and proteinuria.
- Correlation between CEC levels and levels of circulating thrombomodulin and other soluble markers like endoglin and e-selectin.

## Study description

### Background summary

The key role in the pathogenesis of severe preeclampsia is generalized endothelial dysfunction. Circulating endothelial cells are a promising marker of vascular injury in various diseases. Given the potential of CEC as marker and the great need for such markers in the management of severe preeclampsia, the role of CEC in preeclampsia should be defined.

### Study objective

Primary objective:

To demonstrate elevated numbers of CEC in clinically symptomatic patients with severe preeclampsia.

Secondary objectives:

- To analyze the relation of CEC levels with organ damage and dysfunction.
- To analyze the relation of CEC levels with clinical parameters as

bloodpressure and proteinuria.

- Correlation between CEC levels and levels of circulating thrombomodulin and other soluble markers like endoglin and e-selectin.

## **Study design**

Description: Case-control pilot study

Duration: January 2008 till May 2008.

Setting: Department of Obstetrics Erasmus MC, Rotterdam. A total of fifteen women with severe preeclampsia and fifteen healthy pregnant controls will be asked to participate in this study. In clinical patients two extra tubes of blood will be sampled on the occasion of blood sampling. In the control group blood samples will be drawn on an extra occasion.

Criteria for the diagnosis severe preeclampsia:

Criteria published in the protocol on page 8, criteria conform ACAG standards

Parameters that will be noted:

- maternal age, length, weight

- bloodpressure

- laboratory parameters: Hb, Ht, reticulocytes, thrombocytes, ureum, creatinin, uric acid, total bilirubin, sodium, potassium, calcium, magnesium, total protein, albumin, haptoglobin, ASAT, ALAT, LDH and  $\gamma$ GT.

- medication

## **Study burden and risks**

The risks of participation are minimal in both groups.

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Case group:

- diagnosis of severe preeclampsia based upon the ACOG criteria
- written informed consent

Control group:

- ASA class I pregnant patients visiting our out-patient clinic
- written informed consent

### Exclusion criteria

Control group:

- ASA class II or more
- previous pregnancies with placental syndromes as preeclampsia, growth retardation and/or gestational diabetes
- placental syndrome during the index pregnancy

## 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):	01-04-2008
Enrollment:	30
Type:	Actual

## Ethics review

Approved WMO	
Date:	25-03-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL21658.078.08