Ciculating endothelial cells in Preeclampsia

Published: 25-03-2008
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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	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 askes 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, haptoglobulin, ASAT, ALAT, LDH and γGT.
- medication

Study burden and risks

The risks of participation are minimal in both groups.

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

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