Psychosocial sequele after severe, early onset preeclampsia.

Published: 14-02-2008
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Determination of psychosocial effects after severe, early onset preeclampsia for improvement of care of these patients in the future.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31553

Source
ToetsingOnline

Brief title
PEEP (Psychosocial Effects of Early Preeclampsia)

Condition

- Other condition
- Maternal complications of pregnancy
- Psychiatric disorders NEC

Synonym
depression, Post traumatic stress syndrome

Health condition

depressie

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: preeclampsia, psychosocial sequele

Outcome measures

Primary outcome

post traumatic stress syndrome

depression

social consequenses: divorse, job loss

Secondary outcome

none

Study description

Background summary

Preeclampsia is a multiorgan disease, occurring only in gestation and leading to high blood pressure and proteinuria. In the majority of cases it occurs in the third trimester of pregnancy. The etiology of preeclampsia is still obscure but recent knowledge show multifactorial factors with complex interactions between genes and environment. Preeclampsia is the leading couse of maternal death in the Netherlands. The only rational treatment is delivery but remote from term a high rate of neonatal morbidity and mortality will occur. There is little literature available regarding psychosocial sequelae after severe, early onset preeclampsia. Extreme fear, fear of loss of control, frustration and guild are frequently reported emotions during admission and treatment in the hospital. It may lead to extreme stress. We know through personal communications of patients of the dutch preeclampsia association (HELLP stichting) that women suffer longstanding from post traumatic stress symptoms or depression. Frustration among these patients is mainly due to lack of recognision of the symptoms by the medical profession, for whom the purely medical treatment was of major concern at the time of admission. So far, little attention has been paid to psychosocial aspects of severe, early onset

preeclampsia.

Study objective

Determination of psychosocial effects after severe, early onset preeclampsia for improvement of care of these patients in the future.

Study design

Retrospective cohort study

Study burden and risks

Paticipants receive 3 questionnairs, which will take about 30 minutes to fill in. There are no risks. In case women experience emotional distress and/or disturbing memories after participation, psychological care is offered on request.

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

Cases:
Pregnancies of 24-32 weeks' gestational age
Severe preeclampsia according ACOG criteria
Controls:
Spontaneous preterm delivery 24-32 weeks' gestational age in patients with uncomplicated previous medical history

Exclusion criteria

Absence of lethal fetal congenital anomalies

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2008
Enrollment:	440
Type:	Actual

Ethics review

Approved WMO Date:	14-02-2008
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	NL20669.078.07