Changes in cerebral autoregulation and cerebral perfusion pressure in patients with preeclampsia. A pilotstudy with transcranial Doppler sonography (Rotterdam Brain Function Study in Preeclampsia -II)

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To assess if the studied TCD variables of cerebral autoregulation and hemodynamics are abnormal during preeclampsia. And if so, to determine if these changes are large enough to have potential value to determine a threatening cerebral dysfunction in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Encephalopathies
Study type	Observational non invasive

Summary

ID

NL-OMON32356

Source
ToetsingOnline

Brief title
Cerebral autoregulation in preeclampsia

Condition

- Encephalopathies
- Maternal complications of pregnancy
- Vascular hypertensive disorders

Synonym
preeclampsia, toxemia of pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Beschikbaarheid TCD apparaat gesubsidieerd vanuit een IAG subsidie (vanuit de Europese Unie);verleend aan bij G2 genoemd bedrijf,Neuromon BV (stelt TCD apparaat beschikbaar via IAG subsidie)

Intervention

Keyword: Cerebral Hemodynamics, Pre-Eclampsia, Transcranial Doppler Sonography

Outcome measures

Primary outcome

TCD autoregulation variables.

Secondary outcome

Laboratory findings

Clinical course

Study description

Background summary

Information about the cerebral hemodynamic condition in women with preeclampsia can be an important factor to determine the indication for pharmacotherapy or the decision to terminate the pregnancy. At present, these decisions are mainly based on a clinical (neurological) assessment. Apparently, this assessment is suboptimal, since many women with preeclampsia have persistent neurological complaints, such as memory disorders.
Transcranial Doppler sonography is a safe, noninvasive en easy to perform technique to measure and monitor cerebral hemodynamic changes during preeclampsia

Study objective

To assess if the studied TCD variables of cerebral autoregulation and hemodynamics are abnormal during preeclampsia. And if so, to determine if these

changes are large enough to have potential value to determine a threatening cerebral dysfunction in an individual patient with preeclampsia.

Study design

Observational study, including several measurement sessions during and after pregnancy complicated with preeclampsia (and a control group). Transcranial Doppler sonography with additional tests is used to assess the cerebral hemodynamic condition and autoregulation function.

Study burden and risks

Transcranial Doppler sonography, including the intended provocations, is a safe and well-tolerated investigation. Every measurement session will take one hour at most.

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

Preeclampsia

Exclusion criteria

Presence of other central nervous system or vascular disorders.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-06-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	29-04-2008
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	NL21375.078.08