Cognitive function in relation to cerebral blood flow regulation after preeclampsia

Published: 16-01-2009
Last updated: 19-03-2025

To evaluate whether cognitive function of formerly preeclamptics is diminished and correlated with dynamic cerebrovascular control properties using non-invasive measuring techniques (dynamic cerebral autoregulation, neurovascular coupling). Question...

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

Summary

ID

NL-OMON33668

Source
ToetsingOnline

Brief title
Cognition in relation to cerebrovascular regulation after preeclampsia

Condition

- Maternal complications of pregnancy
- Cognitive and attention disorders and disturbances
- Vascular hypertensive disorders

Synonym
cognitive dysfunction after preeclampsia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cerebral blood flow regulation, cognition, preeclampsia, puls wave velocity

Outcome measures

Primary outcome

Presence of cognitive complaints

Neuropsychological test (NPO) scores to map cognitive function

Cerebrovascular control system parameters: NVC-response parameters and parameters describing cerebral autoregulation, in particular in parameters describing the dynamic aspects of the response. For NVC this is damping, rise time and natural frequency and for cerebral autoregulation this is gain and phase as a function of signal frequency

Correlation between degree of disturbance of the cerebrovascular control system and cognitive function in former preeclamptic patients.

Correlation between presence of cognitive complaints and cognitive function (NPO-scores).

Correlation between presence of cognitive complaints and cerebrovascular control parameters.

Secondary outcome

Pulse wave velocity and pulse pressure as a determinant of arterial vessel stiffness

Results of standard duplex -investigation

Study description

Background summary

Although the regulation of cerebral blood flow is known to be altered during preeclampsia, little is known about the state of the control mechanisms after the experience of preeclampsia. Nevertheless, several studies report evidence for formerly preeclamptics having a higher risk to die from stroke and a shorter life expectancy. Furthermore, our previous study shows that neurovascular coupling is abnormal in a subgroup of formerly preeclamptics. The question raised now is whether cognitive function and the persistent cognitive complaints which are regularly reported by former preeclamptics are related to these abnormalities in local blood flow regulation.
A few studies show that cognitive function is disturbed after severe preeclampsia, but discuss that it is not known whether this effect is permanent or temporal and whether it is caused by organic damage. Our working hypothesis is that test-objectified cognitive function of formerly preeclamptics with or without subjective cognitive complaints is correlated with dynamic cerebrovascular control parameters measured by non-invasive techniques for recording cerebral autoregulation and neurovascular coupling. The major objective of the proposed study is to investigate whether cognitive functioning of formerly preeclamptics is diminished and related to control of brain perfusion (brain function). If cognitive function is diminished and related to altered brain function, it could be hypothesized that this cognitive decline is caused by organic cerebral damage and that abnormal CVC parameters may predict a higher risk for future cerebrovascular complications such as stroke.

Study objective

To evaluate whether cognitive function of formerly preeclamptics is diminished and correlated with dynamic cerebrovascular control properties using non-invasive measuring techniques (dynamic cerebral autoregulation, neurovascular coupling). Question is whether these control parameters can serve as screening tool for identifying formerly patients with increased risk on future complications. Comparison of these findings with parameters characterizing systemic blood vessel functioning (pulse wave velocity PWV, pulse transit time PTT) and clinical patient neuropsychological status.

Study design

All subjects will be provided with objective information concerning the research. In case of a positive decision after a number of days thinking over, they will sign a form of consent.
In case the subject wishes, the partner is permitted to accompany her during the recording session. The subject has the right to stop participation to the study at any moment. This information will also be provided before the start of the study.

Study burden and risks

Investigation load and risk for the participants are minimal.
Neuropsychological test battery takes about one hour. For the cerebrovascular tests the participant is lying supine in a bed. During the study of neurovascular coupling the participant has to actively view a dynamic visual stimulus during 40 seconds followed with an eyes closed period of 20 seconds. This sequence is repeated about 10 times. All measurements are non-invasive, do not form a patient load and are painless. Between the different parts of the research (neuropsychological tests, Duplex-investigation, neurovascular coupling registration, cerebral autoregulation registration and pulse wave velocity determination) patients will be given the opportunity to have breaks and drink water. Participation therefore bears no risk.

Ethical aspects
All potential study participants will be informed both in writing and verbally with objective information concerning the scientific research project. Enough time (days to week) will be given to think about participation and to give approval. In case of a positive decision a form of consent will be signed.

It will be made clear that participants may at any moment, without giving reasons and without any further medical consequence, stop their participation to the study.

At any moment the participant will be able to consult an independent physician for further information. The name of this physician is dr. G. Koek (azM).

Participant privacy will be assured and the study data will be coded nameless and anonymously by a coded serial number. Data will be stored for the legally maximal period of medical data backup.
Only direct project staff members will have access to the measurement data. Only these members will know the link between the coded patient data and the patient private data.

It will be made clear that participants may choose to be informed about the results at the end of the project.
The present research is not directly related to disease and will not result in disease related aspects. Despite this, we will inform every participant whether he/she and/or their family doctor wants to be informed about the results of the study. In case abnormalities are found in a subject, which according to the present medical standards should be treated, the general practitioner will be informed.

Publication of research results
Results of the study will be published in peer reviewed scientific papers both

in case of positive but also in case of negative findings. Publication of results will be done according to the CCMO-statement regarding publication policy (march, 2002).
No (research) sponsoring authority has a right of veto regarding publication of research results.

Contacts

Public
Academisch Ziekenhuis Maastricht

P. Debyelaan 25
6229 HX Maastricht
Nederland
Scientific
Academisch Ziekenhuis Maastricht

P. Debyelaan 25
6229 HX Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women who have been diagnosed with severe (clinical admission indispensable) early (< 34 weeks) preeclampsia 0.5-1.5 years ago in their first pregnancy.
Age > 18 years
Informed consent of the patient before participation into the study.

Exclusion criteria

Neurological or cerebrovascular disorders in case history
Kidney function disorder
Use of statines
Psychiatric case history or state (As I and II issues)
Diabetes
Use of anti-depression medicine
Abuse of alcohol and/or drugs.
Smoking or refrained from smoking less than 2 years

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2009
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	16-01-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28661
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	####
CCMO	NL25268.068.08
OMON	NL-OMON28661