Proteomics analysis of cerebrospinal fluid to investigate brain involvement in pre-eclampsia

Published: 15-10-2015
Last updated: 19-04-2024

The objective of the study is to determine the protein profile of cerebrospinal fluid of non-pregnant women using mass-spectrometry.This study is a follow-up project on the previously performed study (LEPRA, CSF and pre-eclampsia, MEC 2007-087). In...

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

Summary

ID

NL-OMON43723

Source
ToetsingOnline

Brief title
LEPRA II (liquor cerebrospinalis and pre-eclampsia)

Condition

- Other condition
- Maternal complications of pregnancy

Synonym
pre-eclampsia

Health condition

neurologische aandoeningen tijdens de zwangerschap

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: cerebrospinal fluid, pre-eclampsia, proteomics

Outcome measures

Primary outcome

The present research aims to obtain a control group of women who are not

pregnant and do not have pre-eclampsia.

The outcome measure of the previous research project was pre-eclampsia: a blood

pressure * 140 mmHg (systolic) and * 90mmHg (diastolic) during at least two

measurements after 20 weeks of pregnancy in combination with proteinuria (* 300

mg / 24 hours or protein / creatinine ratio of * 30 mg / mmol).

Secondary outcome

Not applicable

Study description

Background summary

Pre-eclampsia (PE) is a pregnancy-specific syndrome which is associated with severe morbidity and mortality in both mother and child. The disorder is characterized by hypertension and proteinuria and can affect different organ systems. In severe pre-eclampsia the brains of the mother may be affected. This leads to serious complications such as eclampsia or brain hemorrhage. Also, it is known that pre-eclampsia is a risk factor for the occurrence of cerebrovascular damage in later life. Currently, it is still unknown how the complications in the brain of women with pre-eclampsia occur and difficult to predict which women are at higher risk of developing brain complications.

Study objective

The objective of the study is to determine the protein profile of cerebrospinal fluid of non-pregnant women using mass-spectrometry.

This study is a follow-up project on the previously performed study (LEPRA, CSF and pre-eclampsia, MEC 2007-087). In this project cerebrospinal fluid was collected during the spinal anesthesia procedure before caesarean section. The mass spectrometry analysis has been completed recently. Several differences in protein profile were found between the case and control group. To check the effect of pregnancy on these results, we want to supplement the data with data on the protein profile of cerebrospinal fluid of women who are not pregnant.

Study design

The study design of the LEPRA study was a case-control study. Cases (pre-eclampsia) and controls (healthy pregnant women) were included of which cerebrospinal fluid was collected and analyzed. Clinical information was collected retrospectively from the patient record.

In the current follow-up study cerebrospinal fluid of non-pregnant subjects will be collected exactly in the same manner during the spinal anesthesia procedure for a minor surgical procedure. This minor surgery will be at the daycare of various specialties (eg. gynecology, orthopedics, surgery, etcetera). During the spinal anesthesia procedure 1 ml cerebrospinal fluid will be collected in a tube.

The tubes will be labeled with a study number directly after collection and will be centrifuged within an hour. The supernatant will be distributed over 5 labeled tubes which will be stored in -80 degrees Celsius. After inclusion of 40 samples mass spectrometry analysis will be performed.

The following study participant information which is already obtained during the intake in regular care will be collected:
-date of birth
-any obstetric history
-relevant data from the further medical history
-details of the menstrual cycle and possibly use of oral anticonceptives.

If these data are not available in the medical records they we will ask the study participant to tell us after the informed consent proceduring. There is no follow-up of subjects after the collection of the data. All data are stored under a study number and can only be seen by study staff.

Study burden and risks

Collecting 1 ml cerebrospinal fluid is a minimal burden on the patient, since no additional interventions are needed. There is always leakage of

cerebrospinal fluid during this procedure. The only difference is that we will wait now a few seconds longer to collect the drops in a tube.
The loss of 1 mL of cerebrospinal fluid is the only additional physical burden to the study participant. This can lead to a small change in pressure in the cerebrospinal fluid, which possibly could cause headache. Other complications are not expected.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
Rotterdam 3015 GJ
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
Rotterdam 3015 GJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Non pregnant women of 18 year and older

Exclusion criteria

Pregnant during inclusion
Pre-eclampsia in history
Auto-immune disorders
Oral corticosteroid use
Hemoglobinopathy or clotting disorder
Chronic hypertension or proteinuria
Kidney disorders
Neurologic disorder

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):	19-07-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	15-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	27-06-2016
Application type:	Amendment
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	NL53606.078.15