The applicability of measuring skin-conductance in pre-eclamptic and non-pre-eclamptic pregnant patients.

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Ethical review	Not approved
Status	Will not start
Health condition type	Maternal complications of pregnancy
Study type	Observational non invasive

Summary

ID

NL-OMON35258

Source
ToetsingOnline

Brief title
The skin conductance study.

Condition

- Maternal complications of pregnancy

Synonym
Pre-eclampsia, toxemia of pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pre-eclampsia, Pre-ejection period, Skin-conductance, Sympathetic activity

Outcome measures

Primary outcome

The primary outcome variables will be the mean PEP and SCL. The endpoint is preeclampsia.

Secondary outcome

The secondary study parameters in PART A consist of the mean PEP and mean SCL after the tilt-test in healthy pregnant women and pregnant women at risk of developing preeclampsia.

The secondary study parameters in PART B consists of the mean PEP and mean SCL after the tilt-test in non-pre-elcamptic pregnant women and preeclamptic women when admitted to the obstetrical ward and the mean differences in PEP and SCL during and after magnesium sulphate treatment in preeclamptic patients.

The secondary study parameters will further be the bloodpressure, the ECG and the ICG, and the information received out of diaries patients are writing during treatment with magnesium sulphate.

Study description

Background summary

Preeclampsia is accompanied by an increased basal sympathetic nervous system (SNS) activity (most likely from early pregnancy onwards), contributing to

peripheral vasoconstriction and hypertension. Easily applicable non-invasive measures for an early detection of the increase in SNS activity are direly needed. To prevent eclampsia in preeclamptic women, patients receive magnesium sulphate prophylaxis, of which the effect on SNS activity is unknown but suspected to be substantial.

Study objective

This study aims to test whether non-invasive measures of SNS activity can predict preeclampsia and whether magnesium sulphate in preeclamptic patients reduces the hypersympathetic state. We will quantify SNS activity using the pre-ejection period (PEP). This method is considered the golden standard for the non-invasive measurement of cardiac sympathetic effects. In addition, we want to explore whether skin conductance (SCL) could serve as an alternative for PEP as this method is even simpler and less expensive. To this end, we will measure the SCL and PEP in early pregnant patients at risk for pre¬eclampsia, and in preeclamptic women requiring magnesium sulphate prophylaxis.

Study design

This observational study in subdivided into two parts (PART A, n=20; PART B, n=30).

Study burden and risks

Individuals will not experience a direct benefit of participating in this study. The yield of this study is expected to contribute to better identification and monitoring of high-risk patients destined to develop preeclampsia. In addition we expect this study to increase our insight into the mechanism responsible for the beneficial effect of magnesium sulphate. Participation in this study bares negligible risks for the participants and their unborn child. Clinical care offered to these women with preeclampsia will unaffected by the study. The burden of the study is minimal as the measurement is non-invasive, and is not accompanied by any potentially harmful manipulation.

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

PART A
For this part, we will invite patients to participate, who are already enrolled in the MUPPIT study (Markers of UncomPlicated Pregnancies In 1st Trimester. Protocol 07-222). The MUPPIT study investigates maternal serum markers in the first half of pregnancy in patients that are at risk of developing preeclampsia, to develop a prediction rule for preeclampsia in their current pregnancy. Patients are enrolled at six-seven weeks of pregnancy. Every two weeks blood samples will be taken and bloodpressure will be measured. At twelve weeks of gestational age measurement of the Doppler wave form of the uterine artery takes place. Women will be included in this study after pregnancy conceived by IVF, when they have diabetes type I or type II or when they had severe preeclampsia or fetal growth restriction in their preceding pregnancies. Twin pregnancies and women pregnant of a fetus with chromosomal abnormalities will be excluded.;Participation in the present study only requires approximately 1 hour extra time investment in addition to the MUPPIT-study, mostly spend in relaxely lying on their back on a bed. As we do not subject the participants to any invasive procedures, we feel that the extra time involves minimal extra burden or risk to the participants. These participants already travelled to the hospital because of their participation in the MUPPIT study (no extra travelling time).;Inclusion study
Only women who are pregnant with severe preeclampsia or fetal growth restriction in previous pregnancies will be invited to participate (primi- and multiparous). Recruitment and inclusion takes place at the outpatient clinic when patients have their MUPPIT appointment at 6, 8 or 10 weeks of pregnancy. Measurement takes place at 12 weeks of pregnancy after

completion of the Doppler measurement on behalf of the MUPPIT study.;Control group: Healthy pregnant women, subjected to an ultrasound measurement at twelve weeks of pregnancy. Recruitment takes place by telephone, two weeks before patients have their appointment at the outpatient clinic. Measurement takes place immediately after the ultrasound appointment. Patients will be matched for maternal and gestational age.;PART B
Our population consists of (primi- and multiparous) preeclamptic patients or patients suspected of having preeclampsia. Recruitment takes place at the obstetrical ward of the University Medical Centre Utrecht (UMC Utrecht). Patients are diagnosed with preeclampsia when their arterial blood pressure is * 140/90 mmHg (on at least two separate occasions) accompanied by proteinuria in excess of *300mg/24 hour. They have been normotensive before. They require magnesium sulphate treatment because of increased risk to develop eclampsia. Age can be expected to range from 25 to 40 years. Gestational age varies from 26-40 weeks.;Control group: Recruitment takes place among pregnant patients that are admited at the obstetrical ward because of a pregnancy complication not associated with a hypertensive disorder.

Exclusion criteria

PART A
Patients will be excluded if they have secondary hypertension or chronic diseases that can influence the autonomic nervous system, such as diabetes mellitus, malignancy or neurological disorders. Twin pregnancies and women pregnant of a fetus with chromosomal abnormalities will be excluded as well.;Control group: Patients will be excluded when they have secondary hypertension or chronic diseases potentially affecting the autonomic nervous system, such as diabetes mellitus, malignancy or a neurological disorder. Twin pregnancies and women pregnant of a fetus with chromosomal abnormalities will also been excluded.;PART B
Patients will be excluded if they have secondary hypertension or chronic diseases that can influence the autonomic nervous system, such as diabetes mellitus, malignancy or neurological disorders. Twin pregnancies and women pregnant of a fetus with chromosomal abnormalities will be excluded as well. Furthermore, patients with severe preeclampsia, who need immediately magnesium sulphate prophylaxis (since patients have 24 hours to consider their participation, and measuring will postpone prophylaxis) , will not be included in the study.
Control group: Patients will be excluded if they have secondary hypertension or chronic diseases that can influence the autonomic nervous system, such as diabetes mellitus, malignancy or neurological disorders. Twin pregnancies and women pregnant of a fetus with chromosomal abnormalities will be excluded as well.

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:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Not approved

Date:	28-12-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL38143.041.11