Risk calculation for Pre-Eclampsie and Grwoth Restriction in the First Trimester

Published: 14-11-2013
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A study will be conducted to investigate whether screening for PE and growth restriction not associated with PE in the Dutch setting is feasible.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON39085

Source
ToetsingOnline

Brief title
PERC - Study

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Vascular hypertensive disorders

Synonym
Pre-eclampsia - New-onset Hypertension and Proteinuria in Pregnancy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Growth restriction, Pre-eclampsia, Screening, Uterine artery

Outcome measures

Primary outcome

The main objective of the study is to evaluate the performance of two existing algorithms for the prediction of PE and growth restriction not associated with PE. These algorithms (including the following variables: ethnicity, body mass index (BMI), mean arterial pressure (MAP), lowest Doppler resistance measurement (PI) of both uterine arteries and maternal serum blood markers (PAPP-A and PLGF)) will be tested and other possible combinations of variables will be evaluated for their predictive ability.

Secondary outcome

Secondary objectives:

- Evaluating the learning curve for measurement of the uterine arteries

- Inter and intra- observer variation of measurement of the uterine arteries

- Quality assessment of the measurements of the uterine arteries

- Time needed to collect informed consent, maternal history and measurement of the maternal blood pressure and uterine arteries

Study description

Background summary

Pre-eclampsia (PE) and intra-uterine growth restriction (GR) are major causes of maternal and perinatal mortality and morbidity. Pre-eclampsia occurs in approximately 2% of all pregnancies and is subdivided into early (0.5%) and late PE (1.5%). It is also more common in nulliparae than in multiparae. Early

PE is associated with iatrogenic preterm birth, maternal and neonatal mortality and morbidity. Furthermore, PE is also associated with a fourfold increase in the risk of GR, which is linked to both short-term and long-term health consequences (Odegard 2000). Fetuses affected by GR are at high risk of obesity, cardiovascular disease, hypertension, and diabetes later in life (Barker 1990/2004). Although GR is commonly associated to PE, 5% of GR cases may share the same pathophysiologic background as PE, but without an increase in maternal blood pressure (Karagiannis 2011).
Up to now, women with increased risk of PE/ GR were selected on the basis of their medical history, or based on symptoms that had already manifested (eg. high blood pressure and / or fetal growth restriction). Recent studies have shown that it is possible to screen for PE/ GR, in particular early PE, in the first trimester of pregnancy. The early detection of women at increased risk of PE is desirable to be able to reduce maternal and fetal mortality and morbidity. It also provides the opportunity for researching possible therapeutic options (eg. Aspirin).

Study objective

A study will be conducted to investigate whether screening for PE and growth restriction not associated with PE in the Dutch setting is feasible.

Study design

Prospective cohort study

Study burden and risks

Participation in this study involves an extra blood sample (10 ml tube), taken at the same time blood is drawn for routine pregnancy screening in the first trimester of pregnancy. In addition, an additional 30 minute visit to the ultrasound clinic is planned to measure blood flow in the uterine arteries (non-invasive) and maternal blood pressure. Because the feasibility of screening and of the screenings algorithm is studied, the result of the risk calculation will not be communicated to the women.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen Huispostcode CB20
NL

Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen Huispostcode CB20
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Primigravida
Viable singleton pregnancy < 12 weeks of gestation
Informed consent given

Exclusion criteria

Minors (being under the age of 18)
Incapacitated persons
Not mastering the Dutch language

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2014
Enrollment:	3000
Type:	Actual

Ethics review

Approved WMO Date:	14-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-11-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL40178.042.13