

Analysis of risk factors in early pregnancy to predict pregnancy complications and complications in these women later in life

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This study is focused on determination of risk factors associated with preeclampsia and intrauterine growth restriction, both develop in early pregnancy. These pregnancy complications are associated with cardiovascular diseases in later life. We...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON30528

Source

ToetsingOnline

Brief title

Risk factors in pregnancy and in later life

Condition

- Coronary artery disorders
- Maternal complications of pregnancy

Synonym

intrauterine growth restriction, preeclampsia

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden

Source(s) of monetary or material Support: NWO klinische fellow (Dr de Groot)

Intervention

Keyword: cardiovascular risk factors, prediction and later in life, preeclampsia, pregnancy

Outcome measures

Primary outcome

- lipid-, glucose- and cytokin metabolism (differences between cases and controles) based on the hypothesis of op de hypothese van atherosclerosis for both pregnancy complications as well as cardiovascular diseases in later life

Secondary outcome

none

Study description

Background summary

Despite intensive research there is still an increased maternal mortality over the last decades, the maternal morbidity is unknown and perinatal death does not decline. Pregnancy complications are complex diseases with an unknown cause: interaction of both maternal and paternal genes and environmental factors play an important role.

Preeclampsia is in The Netherlands the most common cause of maternal mortality. Since its cause is unknown the only rational treatment is delivery of the placenta and fetus with the result of preterm birth and high neonatal morbidity and mortality. Preeclampsia is a multi-organ disease of pregnancy clinical characterized by hypertension and proteinuria.

To gain insight in the etiology of preeclampsia before or in early pregnancy we might reduce maternal and neonatal morbidity and mortality. In addition we hypothesis that pregnancy can be considered as a stress test for diseases in later life e.g. development of cardiovascular diseases.

Study objective

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This study is focused on determination of risk factors associated with preeclampsia and intrauterine growth restriction, both develop in early pregnancy. These pregnancy complications are associated with cardiovascular diseases in later life. We will test the hypothesis that both diseases (preeclampsia/ intrauterine growth restriction and cardiovascular diseases in later life) share the pathogenesis of atherosclerosis. With increased knowledge of these diseases using pregnancy as a stress test we might prevent future vascular damage and cardiovascular diseases.

Study design

All women attending the outpatient clinic for preconceptional counseling or antenatal control (before 15 weeks gestation) will be asking to participate. These pregnancies will be followed longitudinal.

Women who develop preeclampsia during pregnancy or intrauterine growth restriction are followed clinically and identified as cases whereas women with uncomplicated pregnancies will be identified as controls retrospectively. Data from the rest (not a case or control) will be analyzed anonymously

Study burden and risks

There are no risk for the participants

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

Pregnancy with gestational age less 15 weeks

Exclusion criteria

< 18 years, language problem, gestational age at first visit > 15 weeks

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):	01-04-2008
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date: 31-05-2007

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL14908.098.07