Healthy heart, healthy pregnancy? How a woman's periconceptional cardiovascular health affects pregnancy outcome.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25494

Source
Nationaal Trial Register

Brief title
HAPPO

Health condition

Preeclampsia
Pregnancy induced hypertension
Fetal growth restriction
Small for gestational age
Cardiovascular disease risk
Pre-eclampsie (zwangerschapsvergiftiging)
Zwangerschapshypertensie (hoge bloeddruk in de zwangerschap)
Foetale groeivertraging
Te laag geboortegewicht
Cardiovasculair risicoprofiel

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam
Source(s) of monetary or material Support: Erasmus MC, Department of Obstetrics and Gynecology

Intervention

Outcome measures

Primary outcome

The primary outcome measure of the HAPPO study is the difference in maternal hemodynamic adaptation to pregnancy, expressed as the trajectory of cardiac output assessed by echocardiography before, during and after pregnancy, between women who do and do not develop placenta-related pregnancy complications

Secondary outcome

The secondary outcome measures are differences in additional indices of maternal hemodynamic adaptation to pregnancy and utero(placental) vascular development between women who do and do not develop placenta-related pregnancy complications.
This includes differences in weight gain during pregnancy, blood pressure, systemic vascular resistance, left ventricular diastolic function, endothelial regulated microvascular function, pulse wave analysis, hemodynamic response to exercise, placental vascular indices, foetal growth parameters (including Doppler measurements) and placenta/placental bed pathology examinations.

Study description

Background summary

Pregnancy requires an adaptive response of the maternal cardiovascular system to meet the demands of the rapidly growing placenta and fetus. A healthy pregnancy outcome largely depends on the adequate establishment of the placental vascularization early in gestation. Consequently, in complicated pregnancies (e.g. preeclampsia and/or intrauterine growth restriction) abnormal placentation is frequently seen. Women who develop such complications have an increased risk for future cardiovascular disease. We hypothesize that latent maternal cardiovascular dysfunction leads to cardiovascular maladaptation to pregnancy, impaired placental vascular development and subsequent pregnancy complications.

This is a prospective cohort study, embedded in the Rotterdam periconception cohort (Predict study) of the Erasmus MC, Rotterdam, the Netherlands, including 200 women with a history of PPC (high risk) and 100 women with an uncomplicated obstetric history (low risk). At five moments (preconception, first-, second- and third trimester, and after delivery), women will undergo extensive examination of the macro- and microcirculatory condition and placental vascular development. Differences in cardiovascular adaptation between women who do or do not develop PPC will be examined. Also, baseline and trajectory differences between high

and low risk women will be studied, independent of subsequent pregnancy outcome.

With this study we aim to provide: 1) more understanding of longitudinal cardiovascular adaptation to pregnancy from the preconception period onwards, as well as placental vascular development; 2) new insights in associations between cardiovascular adaptation, placental health and pregnancy outcome; 3) starting points for future possibilities to optimize cardiovascular and placental health by interventions in clinical validation studies; 4) enable development of more accurate, personalized prevention and treatment strategies for high-risk pregnancies from the earliest moments in pregnancy onwards.

Study objective

Latent maternal cardiovascular dysfunction causes hemodynamic maladaptation to pregnancy, diminished utero(placental) vascularization and, eventually, the development of placenta-related pregnancy complications

Study design

- Preconceptional (maximum of 1 year)

- First trimester of pregnancy

- Second trimester of pregnancy

- Third trimester of pregnancy

- Three months after delivery

Intervention

- Echocardiography

- Non-invasive vascular measurements (post-occlusive reactive hyperemia; pulse wave analysis)

- Cardiopulmonary exercise test with bioimpedance monitoring

- Transvaginal ultrasound (preconceptional, first trimester of pregnancy and after delivery)

- Transabdominal ultrasound (second and third trimester of pregnancy)

- Biomarkers

- Placenta pathological examination

- When delivery takes place by C-section: placental bed biopsies

Contacts

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Eligibility criteria

Inclusion criteria

- Female

- Age above 18 years old

- Current wish to get pregnant

- Previous pregnancy and delivery more than one year ago

- The previous pregnancy was either complicated by preeclampsia/HELLP or fetal growth restriction (high risk group) OR the previous pregnancy was uncomplicated and resulted in a term delivery (low risk group)

Exclusion criteria

- Women unable or unwilling to provide informed consent

- Women currently breastfeeding

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55842
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7394
NTR-old	NTR7602
CCMO	NL66610.078.18
OMON	NL-OMON55842

Study results