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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25494

Bron
NTR

Verkorte titel
HAPPO

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam

Overige ondersteuning: Erasmus MC, Department of Obstetrics and Gynecology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

- Preconceptional (maximum of 1 year)

- First trimester of pregnancy

- Second trimester of pregnancy

- Third trimester of pregnancy

- Three months after delivery

Onderzoeksproduct en/of interventie

- 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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Women unable or unwilling to provide informed consent

- Women currently breastfeeding

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55842
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten