Response to angiotensin II in formerly preeclamptic women. RETAP study.

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In this study, we will investigate whether formerly preeclamptic women exhibit increased angiotensin II sensitivity, which may attribute to renal dysfunction. Furthermore, we will investigate the renal hemodynamics in the short term following a...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26813

Bron
NTR

Verkorte titel
RETAP-study

Aandoening

Formerly preeclamptic women

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoints will be renal (ERPF, GFR and FF) response and systemic response (bloodpressure) to angiotensin II after low and high sodium diet in formerly preeclamptic

patients compared to healthy controls.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

In this study, we will investigate whether formerly preeclamptic women exhibit increased angiotensin II sensitivity, which may attribute to renal dysfunction. Furthermore, we will investigate the renal hemodynamics in the short term following a preeclamptic pregnancy in relation to dietary sodium intake.

Onderzoeksopzet

The study design of this study is a patient-control, cross over study, with a study day after a week of low sodium intake and a week of high sodium intake, with four weeks in between.

Onderzoeksproduct en/of interventie

During one week women will use a low sodium diet (50 mmol sodium/day, 1.2 gram). This will be followed by a week of high sodium diet (200 mmol sodium/day, 4.8 gram) (with four weeks in between). On day 3 and day 6 of each dietary period subjects will collect 24-hour urine to assess dietary compliance and achievement of stable sodium balance.

At the end of both the low and the high sodium diet week, a day of renal function measurements will follow. Baseline blood pressure and renal function will be measured. GFR, ERPF, FF and ECV will be measured by constant infusion of radioactive-labelled tracers: 125-I-iothalamate and 131-I-hippurate. In the afternoon ang II will be infused at a rate of 0.3, 1 and 3 ng/kg/min all during one hour. Both blood pressure and renal hemodynamics will be measured during ang II infusion.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy females with a history of normotensive pregnancy; with a range of one to five years after their pregnancy;

2. Participants with a history of severe preeclampsia; with a range of one to five years after their pregnancy;

3. ≥ 18 years of age;

4. Severe preeclampsia is defined according to ISSHP guidelines.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diabetes mellitus;

2. Diabetes gravidarum in healthy females groups;

3. BMI ≥ 30;

4. Oral contraceptive pill use which can't be temporally stopped;

5. Participants with renal diseases;

6. Participants with cardiovascular diseases;

7. Treatment with anti-hypertensive drug;

8. Blood pressure: systolic > 150, diastolic > 100 mmHg;

9. Pregnant or lactating women;

10. Any surgical or medical condition that in the opinion of the investigator would jeopardize the evaluation of efficacy or safety;

11. History of noncompliance to medical regimens and patients who are considered potentially unreliable.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36569
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2517
NTR-old	NTR2635
CCMO	NL34387.042.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36569

Resultaten

Samenvatting resultaten
N/A