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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26813

Source
NTR

Brief title
RETAP-study

Health condition

Formerly preeclamptic women

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary endpoints will be renal function after preeclampsia, expressed as glomerular filtration rate (GFR), effective renal plasma flow (ERPF), filtration fraction (FF) and extracellular volume (ECV) and changes in RAAS-parameters (plasma renine activity, aldosteron, angiotensins, ACE-activity) in relation to sodiumintake, in formely preeclamptic patients compared to healthy controls.

Study description

Background summary

N/A

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Hanzeplein 1
A.T. Lely
Groningen 9700 RB
The Netherlands
Scientific
Hanzeplein 1
A.T. Lely
Groningen 9700 RB
The Netherlands

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 36569
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A