

Case-control study: prevalence of cardiovascular riskfactors in formerly preeclamptic women and women with uncomplicated obstetric history.

Published: 27-09-2010

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Main objective: Have formerly preeclamptic women, 5 to 10 years post-partum, a higher prevalence of a cardiovascular riskprofile compared to women with uncomplicated pregnancies in history.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON34398

Source

ToetsingOnline

Brief title

Cardiovascular riskfactors in formerly preeclamptic women

Condition

- Heart failures
- Glucose metabolism disorders (incl diabetes mellitus)
- Vascular hypertensive disorders

Synonym

decreased elastic properties of the heart, Diastolic dysfunction

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: AGIKO project

Intervention

Keyword: cardiovascular disease, diastolic dysfunction, preeclampsia, prevention

Outcome measures

Primary outcome

Diastolic dysfunction (echocardiographic/ NT-pro BNP)

Secondary outcome

- 1) Lifestyle (questionnaire)
- 2) Metabolic syndrom or it's components (obesity, hypertension, dyslipidaemia, insulin resistance)
- 3) Endothelial function (FMD)
- 4) Intima Media Thickness (IMT)
- 5) Baroreceptor sensitivity (during Head up Tilt)
- 6) Venous compliance

Study description

Background summary

Large retrospective studies demonstrated an increased cardiovascular risk in women who had preeclampsia during one of their pregnancies, compared to women with uncomplicated pregnancies. The exact pathway for this risk relation between preeclampsia and remote cardiovascular disease remains to be elucidated. Even though preeclampsia is known to initiate endothelial damage, it is considered to be more likely that preeclampsia and cardiovascular disease have common underlying risk factors. The metabolic syndrome, or its components is possibly an important underlying profile. For most risk factors, well proven effective preventative strategies.

Current knowledge is mostly based on retrospective studies in women with diagnosed cardiovascular disease. Structured case-control studies would give more insight into the possible underlying mechanisms explaining the increased cardiovascular risk in formerly preeclamptic women. Cardiovascular disease is in the Netherlands the number 1 cause of death in women. In men incidence of cardiovascular morbidity is slowly declining, in contrast in women this number unfortunately increases. This observation stresses the importance of early recognition of women at risk. Early enough to let these women benefit from proven effective preventative strategies. Pregnancy outcome can therefore help in risk stratification

In the current study we want assess cardiovascular riskprofile in formerly preeclamptic women and healthy controls (women without hypertensive complications in previous pregnancy) (case-control). The 2 groups are age-matched (all between 30-50 years old) and interval after first pregnancy (5-10 years).

Diastolic dysfunction is regarded as one of the first circulatory markers of imminent cardiovascular disease and will therefore serve as primary outcome parameter.

Study objective

Main objective:

Have formerly preeclamptic women, 5 to 10 years post-partum, a higher prevalence of a cardiovascular riskprofile compared to women with uncomplicated pregnancies in history.

Study design

Observational case-control study (both classic and novel cardiovascular risk factors will be evaluated)

Study burden and risks

Study will be performed during a one-stop visit. (duration: 3 hours). Invasive procedures limited to only one venapuncture (taking 25 ml blood), with a small risk of developing a small hematoma. No administration of medication. Participants are not obliged to certain interventions, however in case of certain risk profile, participants will receive explicit advise concerning future cardiovascular risk and possible lifestyle changes in order to reduce certain risks. Counseling will be done according to national standard: "cardiovascular risk management". Based on experience with ultrasound studies, it is known that participants are unlikely to experience any burdens as a consequence of the ultrasound measurements. The cuff surrounding the forearm

during the flow-mediated dilation (FMD) measurement to evaluate endothelial function, can be experienced as unpleasant but (based on previous experience) this measurement is usually well withstood by participants. Other measurements (questionnaires, bloodpressure measurements, weighing and measurement of intima media thickness) are considered to have no risks or burdens for participants.

Time investment is considered minimal for participants. On the other hand, participants can have important health benefit by recognition of certain cardiovascular risks and can initiate well targeted preventative strategies when risk is increased by enhancing healthy lifestyle.

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

Patients:

- women aged 30-50
 - 5 to 10 year post partum
 - preeclampsia in a previous pregnancy ;
- Controls:
- women aged 30-50
 - 5 to 10 year post partum
 - history of vascular uncomplicated pregnancies

Exclusion criteria

- women with diagnosed hypertension in advance of first pregnancy
- diabetes mellitus
- auto immune disease
- pregnancy
- women who do not want to be informed about results of cardiovascular screening

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	278
Type:	Anticipated

Ethics review

Approved WMO

Date: 27-09-2010

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL32728.091.10