

# Modulation of the plasma volume compartment by aerobic exercise in women at risk for hypertensive reproductive complications

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Primary objective: • To investigate whether physical exercise prior to pregnancy in formerly preeclamptic women results in a comparable improvement of vascular and endothelial functioning as in women who had an uneventful pregnancy. Secondary...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Maternal complications of pregnancy
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32865

### Source

ToetsingOnline

### Brief title

Exercise induced circulatory improvement

### Condition

- Maternal complications of pregnancy
- Vascular hypertensive disorders

### Synonym

preeclampsia & latent hypertension

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** NWO (AGIKO aanstelling)

## Intervention

**Keyword:** circulation, exercise, Plasma volume, preeclampsia

## Outcome measures

### Primary outcome

Effect of physical exercise in formerly preeclamptic women on:

- plasmavolume

### Secondary outcome

Effect of physical exercise in formerly preeclamptic women on:

- venous compliance and capacity
- sympathetic tone
- physical fitness (VO2 max)
- Cardiac Output
- Endothelial function measured in a.femoralis, Flow Mediated Dilatation (FMD)
- Glucose lipid profile
- Adaptation RAAS system
- Heartfrequency
- Baseline en maximal flowpatern in arterial system
- observation outcome next pregnancy

## Study description

### Background summary

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In the Netherlands almost 15.000 women each year develop hypertensive complications like preeclampsia during their first pregnancy. In the western world these complications account for the most substantial attribution to neonatal and maternal morbidity and mortality. The exact etiology of this disease cascade is still unknown. There is accumulating evidence that subclinical abnormalities and preexistent haemodynamic, haemostatic and endothelial factors are involved, and thought to have negative impact on placental and endothelial functioning. The same factors are found to be risk factors for cardiovascular incidents and therefore it is not surprising that remotely these women are more at risk for hypertension, cardiovascular disease and stroke. Plasma volume has possibly a central role in the disease cascade, resulting in decreased cardiovascular reserve capacity. Furthermore a low plasma volume is found to be a strong predictor for recurrence of hypertensive complicated pregnancy. Adaptation, like in pregnancy, is for a large extent depending on the functioning of the venous compartment. In formerly preeclamptic women with low plasma volume is the venous compliance and capacitance decreased, furthermore there is sympathetic hyperactivity. This combination reflects a decreased cardiovascular reserve capacity. These women with low plasma volume show a reduced ability to adapt their cardiovascular system to a new pregnancy.

It is known that physical exercise increases plasma volume in healthy adults, also arterial and both venous compliance and capacitance is improved by exercise. Since abnormal circulatory functions are common in formerly preeclamptic women, we want to study the effects of exercise in this specific group, and compare these results with women after an uneventful pregnancy. In preventive perspective it would be beneficial that also formerly preeclamptic women show a circulatory adaption to aerobic exercise, possibly they could improve their haemodynamic profile prior to their pregnancy.

## **Study objective**

Primary objective:

- To investigate whether physical exercise prior to pregnancy in formerly preeclamptic women results in a comparable improvement of vascular and endothelial functioning as in women who had an uneventful pregnancy.

Secondary objectives:

- Which cardiovascular and endothelial parameters are involved in the vascular adaptation to training in women with a history of preeclampsia.
- To study the vascular adaptation in the (next) pregnancy in women with a history of preeclampsia compared with women with a history of an uncomplicated pregnancy, after improvement of their physical condition by exercise training.

This study is important in order to get a better understanding of the vascular and endothelial factors involved in preeclampsia and the effects of training on this profile. Results of this study can contribute to the improvement of

preventing hypertensive complications in pregnancy and reduction of life time risk of cardiovascular disease in formerly preeclamptic women.

To achieve these goals we defined the following hypotheses:

- Formerly preeclamptic women are/have compared to women with a history of an uneventful pregnancy:

1. have a decreased capability to expand their plasma volume compartment by aerobic exercise

2. a: have a decreased capability to increase their venous compliance and capacitance by aerobic exercise

b: have a decreased capability to mobilize unstressed venous volume in reaction to orthostatic stress

3 have a decreased capability to reduce sympathetic hyperactivity by aerobic exercise

4. have a decreased capability to improve their arterial functioning by aerobic exercise

5. have a reduced exercise tolerance and have a decreased capability to improve this by aerobic exercise

- Formerly preeclamptic women with low plasma volume are compared with women who had an uneventful pregnancy less capable of adapting their venous and arterial system to the new pregnancy but can improve this by physical exercise

## **Study design**

Prospective intervention study, with follow-up of patients after the intervention period of 12 weeks

## **Intervention**

Aerobic training (twice weekly, à 50 minutes); training is customized to personal physical condition (70% VO<sub>2</sub> max). Training period: 12 weeks

## **Study burden and risks**

The burden for participants is mainly the time intensiveness of the study (training twice a week and three measurements in twelve weeks time).

The measurements are minimal invasive, minimized to two iv lines in both forearms.

There is no medication given that is aimed to have health effects. To study the vascular and endothelial function, 3 substances are given (voluven, dextran and glyceryl trinitrate), these substances are well known and are without any known medical risks, although it is known that humans can react allergic to dextran. The dosage of dextran used in this study is low, therefore unwanted reactions

can be expected to be mild. In case of reaction, further administration will be prevented. The insufflation of the cuffs around arm and leg are unpleasant.

Risks associated with this study is considered to be minimal.

## Contacts

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### Scientific

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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: normotensive primipara women with prior history of preeclampsia (defined as proteinuria of protein/creatinine ratio > 30 g/mol; and hypertension systolic > 140 mmHg, diastolic > 90 mmHg; diagnosed before 37 weeks gestation). ;controls: normotensive primipara women with a history of an uneventful pregnancy

## Exclusion criteria

Incapability to cope with physical exercise  
insulin dependant diabetes mellitus  
auto-immune disease  
Use of medication known to interfere with vascular and endothelial function  
Pregnancy

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-05-2009
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO	
Date:	06-11-2008
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	NL24246.091.08