# Excercise induced circulatory improvement in formerly preeclamptic women

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To test the hypothesis that in formerly preeclamptic women with a low plasma volume a month physical excercise improves vascular and hemodynamic functions.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Maternal complications of pregnancy |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON29785

**Source**
ToetsingOnline

**Brief title**
excercise induced circulatory improvement

### Condition

- Maternal complications of pregnancy
- Vascular hypertensive disorders

**Synonym**
latent hypertension

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** circulation, excercise, plasma volume, preeclampsia

## Outcome measures

### Primary outcome

improvement of plasma volume > 10%

### Secondary outcome

improvement of vascular and endothelial function in response to excercise

# Study description

### Background summary

In the Netherlands, about 15% of all first pregnant women develop hypertensive complications, of which preeclampsia and general seizures may be considerd to be the most severe endpoints. In the western world, these complications account for a substantial maternal and fetal/neonatal morbidity and mortality. Evidence is accumulating that these disorders are superimposed upon a preexisting hemodynamic or hemostatic risk condition. These factors negatively affect placental and vascular functioning. Considering these premorbid riskfactors, it is not surprising that remotely these women are more involved in hypertension, cardiovascular disease and stroke. A central position in the circulatory problems may arise from a relatively small venous compartement (plasma volume compartement), affecting cardivascular reserve capacity and associated with sympathetic overactivity, reduced arterial compliance and elevated resting cardiac output. Clinically, a reduced plasma volume compartement is associated with an increased risk to develop gestational hypertensive problems such as preeclampsia and fetal growth restriction. By positively affecting this amount of plasma volume, this may contribute to a reduction in these hypertensive complications.

### Study objective

To test the hypothesis that in formerly preeclamptic women with a low plasma volume a month physical excercise improves vascular and hemodynamic functions.

### Study design

in this pilot study we intend to include 10 women. Considering a power 90% and

a type I error 5% we will be able to detect a difference 10-12% in plasma volume. We intend to alter the plasma volume compartement by use of a standardised physical excercise program in which the training will be to a maximum of 70% of that maximal reached intensity in these women. The response to this training program will be evaluated as a function of change in
plasma volume
resting and excercise induced cardiac output
oxygen consumption during excercise
venous capacity and compliance
arterial compliance
flow mediated vasodilation
biochemical changes in VWF ag and fibronectin, hs CRP and micro-albuminuria
hemoglobin count
blood pressure and heart rate (excercise induced)
weight and lean body weight

**Intervention**

physical excercise; first two weeks twice a week 1 hour at max 70% of the VO2max the last two weeks three times a week at 70% of the VO2max

**Study burden and risks**

The training program is in a way a life style change. The insertion of the two venous catheters uposes a minimal dyscomfort, the protocol takes time but may also be considerd as moderate dyscomfort. We consider the total protocol as moderate strain, in which the life style adjustments may be considerd to be the most meaningfull.

# 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

prior history of preeclampsia

## Exclusion criteria

incapability to cope with physical activity

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2006 |
| Enrollment: | 10 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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|---|---|
| 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 | NL12203.091.06 |