

# PREVENTIVE LEG CROSSING AND OBJECTIVE ORTHOSTATIC TOLERANCE II

## Testing efficacy in patients with recurrent vasovagal syncope

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We hypothesize that leg crossing increases orthostatic tolerance of patients with recurrent orthostatically induced vasovagal syncope.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30047

### Source

ToetsingOnline

### Brief title

PREVENTIVE LEG CROSSING AND OBJECTIVE ORTHOSTATIC TOLERANCE II

### Condition

- Other condition

### Synonym

fainting, swooning, vasovagale syncope

### Health condition

vasovagale reacties

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W, Nederlandse Hartstichting

## Intervention

**Keyword:** fainting, low blood pressure, syncope

## Outcome measures

### Primary outcome

Orthostatic tolerance

### Secondary outcome

na

## Study description

### Background summary

Aiming for leg crossing as a prophylaxis for vasovagal reactions to occur \*and thus to upgrade its applicability from tertiary to secondary prevention, the recent study entitled \*Preventive leg crossing and objective orthostatic tolerance\* showed that in healthy volunteers (without recurrent vasovagal syncope) leg crossing improves orthostatic tolerance greatly. The study was unable to show a beneficial effect of oral placebo on orthostatic tolerance.

### Study objective

We hypothesize that leg crossing increases orthostatic tolerance of patients with recurrent orthostatically induced vasovagal syncope.

### Study design

In patients with recurrent orthostatic vasovagal syncope, a tilt table test will be performed twice, with addition of \*lower body negative pressure\* (LBNP). LBNP tilting is a reliable method of determining orthostatic tolerance in healthy subjects with a high reproducibility. Orthostatic tolerance will once be studied without intervention and once with leg crossing

as a permanent intervention.

## **Intervention**

leg crossing (physical manoeuvre)

## **Study burden and risks**

The risk in this study is that of an ongoing vasovagal syncope after terminating the tilt protocol, possibly with temporary vagally mediated bradycardia or asystole. Such asystolies are very rare in clinical routine tilt tests (<0,5%) and self limiting. Fatalities during tilt tests have never been reported.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

Age: 18-50 years; Inclusion criteria:

- Clinical diagnosis of classical vasovagal syncope, based on the history and positive tilt test or
- Non-classical vasovagal syncope and a positive clinical tilt test. ; - \*2 syncopic episodes in the last 2 years

## Exclusion criteria

Exclusion criteria: ; - (suspected) pregnancy

- (suspected) cardiovascular disease, other than recurrent vasovagal syncope
- presence of any circumstance that is likely to interfere significantly with normal orthostatic tolerance and/or the use of LBNP and/or the use of leg crossing.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-01-2007

Enrollment: 20

Type: Anticipated

## Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL11877.018.06