

# Five year follow up of duplex investigations in young patients with a history of suspect venous disorders

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Follow up of 38 patients who had a duplex investigation in the past when they were 18 years old or younger.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Approved WMO               |
| <b>Status</b>                | Recruitment stopped        |
| <b>Health condition type</b> | Venous varices             |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON43227

### Source

ToetsingOnline

### Brief title

Duplex follow up

### Condition

- Venous varices

### Synonym

thrombosis and reticular veins, Venous disorders

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Rijnstate Ziekenhuis

**Source(s) of monetary or material Support:** Eigen kosten/middelen.

## Intervention

**Keyword:** Chronic venous disorder, Duplex investigations, Venous complaints, Venous insufficiency and children

## Outcome measures

### Primary outcome

Duplex results after 5 years

### Secondary outcome

Changes in clinical venous disorders (varicose veins) after 5 years

## Study description

### Background summary

A large number of patients develop varicose veins and venous disorders during life. Venous disorders in children are seldom seen and described and relatively often concern only thrombosis and reticular veins. It might be that chronic venous disorders (CVD) in children and young adults is underestimated, because they show less clinical disorders. Young patients with venous complaints might have a higher risk developing venous disorders at a relatively young age. Since we studied a group of 38 patients with venous complaints five years ago (thrombosis and varicose veins), we were interested how venous system had developed in time. Most patients of these group are adults now. Literature does not show follow up studies of young patients with chronic venous disease. If venous disorders increase in five years, it might be an suggestion to check young patients with venous disorders more regularly.

### Study objective

Follow up of 38 patients who had a duplex investigation in the past when they were 18 years old or younger.

### Study design

Observational follow up study after 5 years

The subjects will visit the clinic for the following tests:

- Complete questionnaire
- Assessment of the legs

- Duplex investigation

A visit takes about 30 to 45 minutes.

### **Study burden and risks**

The main burden is a visit to the outpatient clinic for a duplex investigation. It is one visit. In this visit there will be a duplex investigation and a questionnaire, which is asked to all patients with venous disorders. During the duplex investigation clinical disorders of venous disease will be described. The benefit for the patient is an update of their venous anatomical situation. Duplex investigation is non-invasive, not painful, has no risks. Most patients of this study had more than 1 duplex investigation in the past.

## **Contacts**

### **Public**

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Arnhem 6815 AD  
NL

### **Scientific**

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Wagnerlaan 55  
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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)

Adolescents (16-17 years)

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

## Inclusion criteria

38 patients, who had their first duplex investigation under 18 years

## Exclusion criteria

No

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-12-2017

Enrollment: 38

Type: Actual

## Ethics review

Approved WMO

Date: 30-03-2016

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     | NL56932.091.16 |