# New duplex criteria for in-stent restenosis in aotro iliac arteries. a long term follow up duplex post stenting trial.

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The aim of the proposed study will determine new duplex ultrasound velocity (DUS) criteria for reference/normal values and in-stent re-stenosis after aorto-iliac stenting.

**Ethical review** Approved WMO

**Status** Pending

**Health condition type** Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Study type** Observational invasive

# **Summary**

#### ID

NL-OMON30191

#### Source

ToetsingOnline

#### **Brief title**

New duplex criteria

#### **Condition**

Arteriosclerosis, stenosis, vascular insufficiency and necrosis

#### **Synonym**

atherosclerose, peripheral artery disease

### Research involving

Human

### **Sponsors and support**

**Primary sponsor:** Ikazia Ziekenhuis

Source(s) of monetary or material Support: Maatschap chirurgie Ikazia ziekenhuis

Intervention

**Keyword:** aorto-iliac stenting, Duplex, re-stenosis

**Outcome measures** 

**Primary outcome** 

The patients shall undergo an Ankle-Brachial Index (in rest and after treadmill

test) (ABI), DUS and blood analysis.

Within a month an angiography (DSA) with pressure measurement (IAPM) shall be

performed.

With duplex ultrasound (DUS) the peak systolic velocity (PSV), in pre, in and

post stent area shall be measured. The elevation in blood velocity shall be

valued as PSV ratio (in-stent/pre-stent).

Within a month an angiography (DSA) with pressure measurement (IAPM) shall be

performed. During intra arterial pressure measurement (IAPM), the mean systolic

pressure shall be measured in pre, in and post stented area.

IAPM is generally known as the \*golden standard\*.

The PSV ratio can be compared with the pressure loss over the stented area and

the DSA (stenosis grade).

These results can serve as reference values.

**Secondary outcome** 

Angiographic grade (morphologic view) of stenosis will also be compared with

the PSV ratio measured with DUS.

Ankle-brachial index test (ABI): In rest and after treadmill test. (see chapter

All patients will undergo an ABI in rest and after treadmill test in order to determine the Rutherford classification of peripheral artery disease. This classification is the current standard for categorizing clinical assessment.

Blood analysis.

Blood analysis shall be performed for sub analysis.

If a second pressure loss is being measured after a PTA or selective stenting and new DUS PSV ratio are being measured. These values, The  $\Delta$  PSV ratio versus the  $\Delta$  pressure loss, shall be calculated and transformated in a x and y axis table.

# **Study description**

### **Background summary**

Recent articles have showed that duplex ultrasound (DUS) criteria after carotid artery stenting (CAS) have not been well-established. A potential source of error in using DUS after CAS is that reduced compliance in the stented artery may result in elevated velocity measured in peak systolic velocity (PSV). Also due to re-stenosis elevated velocities can measured. Therefore, the surveillance in patients with aorto-iliac stents is not optimal.

### Study objective

The aim of the proposed study will determine new duplex ultrasound velocity (DUS) criteria for reference/normal values and in-stent re-stenosis after aorto-iliac stenting.

### Study design

It will be a clinical cohort study.

### Study burden and risks

The patients shall undergo an ABI and DUS. These tests are non-invasive with no burden for the patients.

A DSA is an invasive test and is generally known as the golden standard. Due to the fact that it is an invasive test it carries some risks. But it is very important to examine these duplex criteria in order to improve the surveillance in these patients.

### **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

All people who have had an aorto-iliac stent due to claudication intermittens

### **Exclusion criteria**

impossibility to follow up Persistent pressure loss after stenting

# Study design

### **Design**

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 30-06-2006

Enrollment: 140

Type: Anticipated

### **Ethics review**

Approved WMO

Date: 15-06-2006

Application type: First submission

Review commission: TWOR: Toetsingscommissie Wetenschappelijk Onderzoek

Rotterdam e.o. (Rotterdam)

# **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 NL12693.101.06