New duplex criteria for in-stent re-stenosis 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

6.2)

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 Δ PSV ratio versus the Δ 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

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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

informed consent

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