Long term follow up in patients with intermittent claudication randomized for supervised exercise training or endovascular revascularization

Published: 17-11-2009
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To evaluate the long-term clinical effectiveness of patients with IC randomized for supervised exercise training orendovascular revascularization.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lifestyle issues
Study type	Observational non invasive

Summary

ID

NL-OMON33307

Source
ToetsingOnline

Brief title
CETAC- follow up

Condition

- Lifestyle issues
- Vascular injuries

Synonym
Intermittent claudication, limping

Research involving
Human

Sponsors and support

Primary sponsor: Ikazia Ziekenhuis

Source(s) of monetary or material Support: collectebusfondsen ikazia ziekenhuis

Intervention

Keyword: exercise, Intermittent claudication, revascularization, walking distance

Outcome measures

Primary outcome

maximum walking distance

Secondary outcome

preference based utilities (EQ-5Dand Rating Scale), health status QoL scores

(SF-36 and VascuQol), ankle-brachial index, maximum painless walking distance,

clinical success, risk factor score, number of events, patency rates

Study description

Background summary

Peripheral arterial disease (PAD) is a chronic atherosclerotic occlusive disease of the lower
extremities. The first clinical symptom in patients with PAD is intermittent claudication (IC) (i.e.,
Rutherford category 1, 2, or 3), which affects appoximately 275 000 people older than 50 years in
the Netherlands alone. Despite developments in treatment for Intermittent claudication, the standard treatment is not optimal. Results from studies directly comparing long-term effects of supervised exercise training and endovascular
revascularization are scarce. The CETAC study, a single centre RCT perfomed at Ikazia hospital, compared
endovascular revascularization to supervised exercise training.
The CETAC study demonstrated that after both treatments, functional capacity and quality-of-life scores
increased after 6- and 12-months follow-up in patients with IC. The improvement in maximum walking distance
,however, was significantly better after supervised exercise compared to endovascular revascularization
after 12 months follow-up. convincing evidence on long term effectiveness of

supervised exercise training compared to revascularization is lacking.Therefore, the added value of the continuation of the prospective CETAC study will be the long-term clinical effectiveness of supervised exercise training compared to revascularization in patients with IC after a mean follow up of 5 years.

Study objective

To evaluate the long-term clinical effectiveness of patients with IC randomized for supervised exercise training or endovascular revascularization.

Study design

Long-term follow up study of a RCT (CETAC study)

Study burden and risks

This study will be non-invasive for the participants and no risks are associated with participation.

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

As this study is a continuation of the CETAC study the inclusion criteria have been described extensively in the CETAC study.

Exclusion criteria

As this study is a continuation of the CETAC study the exclusion criteria have been described extensively in the CETAC study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	151
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	17-11-2009
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	NL27981.101.09