Additional exercise therapy in patients with peripheral arterial disease: The value of supervised exercise therapy after invasive treatment of peripheral arterial disease.

Published: 04-01-2007
Last updated: 09-05-2024

The objective of this study is to investigate what the value is of SET after a radiological or surgical intervention for peripheral arterial disease in the aorto-iliacal, femoro-popliteal and crural segments in comparison with a control group.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON30240

Source
ToetsingOnline

Brief title
NETP Extra

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
intermittent claudication, Peripheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Angioplasty, Bypass, Exercise therapy, Peripheral arterial disease

Outcome measures

Primary outcome

The primary outcome is the absolute claudication distance in meters. This is

the distance at which a patient can not walk any further, and is determined by

a standard treadmill protocol.

Secondary outcome

Additional outcomes are initial claudication distance, quality of life,

fontaine stadium, ankle brachial index, vascular risk factors,

re-interventions, number of attended sessions, patency and mortality.

Study description

Background summary

Treatment of peripheral arterial disease consists of vascular risk factor management and, dependent on the severity of the disease, exercise therapy, and either radiological or surgical intervention. After invasive treatment, many patients keep complaints, or complaints return, despite the fact that the treated segment is still patent.
Supervised exercise therapy (SET) has been proved to be an effective treatment for patients with intermittent claudication, with a significant increase in maximal walking distance. Further, exercise therapy contributes to an improvement in quality of life, a delay in disease progression and an improvement of the vascular risk profile.
Research on SET after an invasive intervention is rare. In one study, the effect of SET after surgical treatment on walking distance was determined. The initial claudication distance increased significantly in the exercise group,

compared with surgical treatment alone.
In June 2004, the Network for Exercise Therapy Parkstad (NETP) was implemented in Heerlen and its environs. The physiotherapists of this network provide community based SET according to the protocol of the Royal Dutch Society of Physiotherapy. The web based database, which is a part of the NETP, was retrospectively searched for patients who started SET within 2 months after a radiological or surgical intervention. Seventeen patients fulfilled these criteria, and after 1, 3, 6 and 12 months, there was a significant increase in both initial claudication distance (ICD) and absolute claudication distance (ACD).

The expectation is that SET, immediately offered after an invasive intervention for peripheral arterial disease, influences walking distance and quality of life. Further, a positive influence on vascular risk factors and the frequency of re-interventions is expected.

Study objective

The objective of this study is to investigate what the value is of SET after a radiological or surgical intervention for peripheral arterial disease in the aorto-iliacal, femoro-popliteal and crural segments in comparison with a control group.

Study design

When, on medical grounds, a decision has been made to perform an invasive intervention, patients are randomly assigned to regular care or regular care without additional SET. Stratification takes place, according to localisation (aorto-iliacal, femoro-popliteal, crural).
Patients assigned to SET receive exercise therapy from a trained physiotherapist of their own choice, according to the guideline of the Royal Dutch Society of Physiotherapists. Follow up of the ICD and ACD takes place at baseline, after invasive intervention, and after 1 month, 3 months, 6 months and 12 months. Patients in the control group receive the same follow up from a trained physiotherapist.
Every patient receives the regular follow up in the hospital according to the CBO-consensus at baseline, and after 3, 6 and 12 months.

Intervention

For 12 months the intervention group receives exercise therapy with supervision from a trained physiotherapist, according to the protocol of the Royal Dutch Society of Physiotherapists.

Study burden and risks

Patients who participate in this study receive regular patient care. Patients benefit from the fact that vascular risk management is well organised.
The questionnaires are an extra burden for the patients, although the questionnaires are short. The intervention group follows 12 months of SET. The potential cardiac risk is screened and in case of doubt a cardiologist is asked for his professional opinion. At start, SET is time consuming, but the number of sessions is gradually decreasing. Benefits of exercise therapy are better condition, potential weight loss, increasing strength and a more positive risk factor profile.

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

Patients with peripheral arterial disease, fontaine stadium 2, 3, or 4, with an indication for

angioplasty or surgical reconstruction

Exclusion criteria

Disability to exercise as a result of peripheral arterial disease, serieus cardiac or pulmonary comorbidity (NYHA 3 and 4), other comorbidities that disable exercise therapy and inadequate knowledge of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2007
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL15104.096.06