Supervised Exercise Therapy or Endovascular Revascularization for Intermittent Claudication due to an iliac artery obstruction.

Published: 26-11-2009
Last updated: 04-05-2024

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Ethical review	-
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON39606

Source
ToetsingOnline

Brief title
SUPER-study

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Fontaine II, Peripheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw doelmatigheidsonderzoek projectnr. 171102025

Intervention

Keyword: Endovascular revascularization, Iliac artery obstruction, Intermittent claudication, Supervised exercise therapy

Outcome measures

Primary outcome

The primary objective is to compare initial PTA with supervised exercise

therapy for patients with disabling intermittent claudication due to an iliac

artery lesion with respect to patients* ability to walk and health related

quality of life.

Secondary outcome

Secondary objectives are to assess the level of functional status following

both treatments and to assess the cost-effectiveness and cost-utility of

percutaneous revascularization from a societal perspective with supervised

exercise therapy as the best alternative treatment available.

Study description

Background summary

Treatment of patients with IC is aimed at secondary prevention of cardiovascular events by control of risk factors for atherosclerotic disease, and to improve walking distance and subsequently quality of life. Supervised exercise therapy (SET) can effectively improve pain free walking distance. Percutaneous Transluminal Angioplasty (PTA) as initial therapy is a durable and an effective treatment for iliac artery obstructions with 4 year patency rates of 70%. However the most optimal initial therapy for intermittent claudication

due to an iliac artery obstuction is unclear.

Study objective

The primary objective is to compare initial PTA with supervised exercise therapy for patients with disabling intermittent claudication due to an iliac artery lesion in terms of mobility, functional status, health related quality of life and cost- effectiveness.

Study design

A multicenter randomized controlled trial.

Intervention

One group of 200 patient will recieve supervised exercise therapy.
One group of 200 patients will recieve endovascular revascularization.
All patients will recieve optimal medical treatment.

Study burden and risks

Patients will be randomized for one out of two treatment groups. Both treatment strategies are accepted as initial treatment for intermittent claudication. The risks associated with participating are the normal risks of complication of treatment, there are no additional risks. Patients are needed to attend three extra follow-up moments where they are asked to fill in three questionnaires and some non-invasive hemodynamic measurements will be done. There are no benefits associated with participating.

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

- Age >= 18 years
- Disabling claudication as defined by surgeon based on patient history.
- Ankle/Brachial Index < 0.9 or drop in ABI > 0.15 after exercise test.
- Hemodynamic stenosis of the common or external iliac artery on Color Duplex Scanning (PSV ratio >= 2.5 or EDV >= 0.6 m/s) or on MRA (> 50% stenosis) or occlusion of the common or external iliac artery on Color Duplex Scanning (PSV 0 m/s) or on MRA
- Iliac artery lesion and a concomitant stenosis in the superficial femoral artery defined as stenosis > 50% by Color Duplex Scanning (PSV ratio >= 2.5 or EDV >= 0.6 m/s) or on MRA, or occlusion on DS (PSV 0 m/s) or MRA.
- Lesion classified A, B or C according to the TASC classification of aorto-iliac lesions.
- Patient is able to walk at least 2 minutes on a treadmill at 3.2 km/h and 10% incline
- The Maximum Walking Distance on a treadmill < 300 meters

Exclusion criteria

- Life expectancy < 3 months
- Unable to complete self-reported questionnaires (insufficiently reading or speaking the Dutch language, cognitive disorders, etc).
- Known contrast allergy
- Pregnancy
- Contra-indication for anticoagulant therapy
- Duration of current complaints < 3 months
- Occlusion of the common femoral artery at the affected side
- Patient participates in another study
- Heart failure or Angina Pectoris NYHA III or IV.
(NYHA III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea

NYHA IV: Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased)
- Patient previously received SET according to KNGF guidelines
- Renal insufficiency (serum creatinin > 150 micromol/l)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	03-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL30212.018.09