Exercise versus angioplasty for claudication based on iliac artery lesion

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Primary objective of this study is to assess the treatment outcomes in terms of mobility parameters.Secondary objective is to assess the level of functional status and health-related quality of life.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31237

Source
ToetsingOnline

Brief title
EVACIA-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: eigen research middelen

Intervention

Keyword: Exercise therapy, Iliac artery lesion, Intermittent claudication, Percutaneous transluminal angioplasty

Outcome measures

Primary outcome

Primary endpoint is to assess the treatment outcomes of percutaneous

revascularization and exercise therapy in terms of mobility parameters.

Secondary outcome

Secondary objective of this study is the level of functional status and

health-related quality of life in patients with disabling intermittent

claudication due to an iliac artery lesion after exercise training or

percutaneous revascularization.

Study description

Background summary

The initial treatment of intermittent claudication is exercise therapy and secondary prevention of cardiovascular disease. This exercise training is proved to be effective for formation of collaterals. However, in case of an iliac artery lesion the benefit is not unquestioned. Some practitioners prefer percutaneous revascularization as the initial treatment. The optimal initial therapy remains unclear.

Study objective

Primary objective of this study is to assess the treatment outcomes in terms of mobility parameters.
Secondary objective is to assess the level of functional status and health-related quality of life.

Study design

A prospective randomized unblinded controlled trial.

Intervention

One group (115 patients) will get percutaneous revascularization.
One group (115 patients) will get supervised exercise training.
All patients will get 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

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

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 in discussion with the patient.
- Hemodynamic stenosis of the common or external iliac artery on duplex scanning (PSV ratio * 2.5 or EDV * 0.6 cm/s) or on MRA (> 50% stenosis) or occlusion of the common or external iliac artery on duplex scanning (PSV 0 m/s) or on MRA
- Lesion classified A, B or C according to the TASC classification of aorto-iliac lesions

Exclusion criteria

- Life expectancy < 3 months
- Unable to fill-in self-reported questionnaires (insufficiently reading or speaking the Dutch language, cognitive disorders, etc).
- Legally incompetent adults
- 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

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: Pending

Start date (anticipated):	01-11-2007
Enrollment:	230
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

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	NL18167.018.07