

Cost-effectiveness of treatment strategies for intermittent claudication

Published: 12-01-2010

Last updated: 17-08-2024

To evaluate the cost-effectiveness, from the perspectives of the health care system and of society at large, of supervised exercise compared to endovascular revascularization plus supervised exercise as first-line treatment of IC.

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

Summary

ID

NL-OMON35031

Source

ToetsingOnline

Brief title

Cost-effectiveness of treatment strategies for intermittent claudication

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

Intermittent claudication (IC)

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: endovascular revascularization, Intermittent claudication, supervised exercise

Outcome measures

Primary outcome

Primary: maximum walking distance; Secondary: preference based utilities (EQ-5D and Rating Scale), health status QoL scores (SF-36 and VascuQoI), ABI, maximum painless walking distance, clinical success, therapeutic and total costs, CVD risk factor score, number of events; all outcomes after 1-, 6-, and 12-months follow-up.

Secondary outcome

NA

Study description

Background summary

Intermittent claudication (IC) is the first symptomatic manifestation of peripheral arterial disease and affects 275 000 people older than 50 years in the Netherlands alone. Despite developments in treatment for IC, the standard treatment is not optimal. This project examines alternative treatments.

Study objective

To evaluate the cost-effectiveness, from the perspectives of the health care system and of society at large, of supervised exercise compared to endovascular revascularization plus supervised exercise as first-line treatment of IC.

Study design

Prospective multicenter Randomized Controlled Trial

Intervention

1. Supervised exercise at a physical therapy center;
2. Endovascular revascularization plus supervised exercise at a physical therapy center

Study burden and risks

Endovascular revascularization and supervised exercise are standard treatments. There is no risk.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Rutherford category 1, 2, or 3

2. Maximum pain-free walking distance <350m
3. ABI <0.9 at rest or ABI decreasing by >0.15 after the treadmill test;
4. ≥1 vascular stenoses of >50% diameter reduction at the iliac or femoro-popliteal level.
5. Informed consent

Exclusion criteria

1. Abdominal aortic aneurysm
2. Life-incapacitating cardiac disease (NYHA classification III and higher);
3. Multilevel disease (i.e., same-side stenoses at both the iliac and femoral levels, requiring multiple revascularization procedures)
4. Isolated tibial artery disease
5. Lesions deemed unsuitable for revascularization
6. Prior treatment for the same lesion (including exercise training)

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):	01-08-2010
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO

Date:	12-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	08-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (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	NL30125.078.09