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Comparing Exercise Training and Angioplasty for Claudication: a randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/08/2021	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1361; NL163 (NTR199)

Study information

Scientific Title
Comparing Exercise Training and Angioplasty for Claudication: a randomised controlled trial

Acronym
CETAC

Study objectives
There remains still uncertainty surrounding the effectiveness of the treatment strategies in patients with intermittent claudication. Therefore, the proposed study will evaluate the relative impacts of exercise training versus percutaneous transluminal angioplasty in patients with iliac and femoro-popliteal vascular pathology on the quality of life and the Maximum Painless Walking Distance (MPWD) after six months and one year follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Intermittent claudication

Interventions
Percutaneous Transluminal Angioplasty (PTA):
PTA is an invasive procedure with catheterisation and Digital Subtraction Angiography (DSA). The procedure requires an arterial puncture and a four to six hour period of bed rest when it is finished.

Patients are invited to the department of radiology. PTA will be performed using a conventional guidewire and balloon catheter technique. The lumen of the stenotic or occluded artery has to be overdilated by 10% above normal. If the pressure measurement shows a successful result (no

pressure gradient of more than 15% or less than 10 - 15 mmHg), a post-procedural angiography will be performed to show morphologic success. Intra-arterial iodinated contrast is administered through the catheter, as well as heparin. Post-procedural Ascal therapy (100 mg per day) will be given for the remaining lifetime.

Hospital-based exercise:
Hospital-based exercise is a non-invasive treatment and will be conducted twice a week, 30 minutes each session, on a walking treadmill during 24 weeks. Each training session will be supervised by a vascular technician.

Walking treadmill exercise will be initiated at a low treadmill work load of 3.5 km/h, 0% grade. Patients walk until claudication pain occurs, at which time patients will rest until the pain subsides.

Exercise and rest periods are repeated throughout each training session. If a patient is able to walk eight to ten minutes at the initial work load, the grade will be increased by 1-2% or the speed will be increased by 0.5 km/h as tolerated.

If the MPWD does not improve, the vascular technician should try to find the possible cause (e.g. insufficient training, bad condition) and the patient has to be motivated to continue the training programme.

All patients are instructed to walk for at least 30 minutes three times a week outside the hospital setting.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Quality of life during follow-up:
The aim of exercise training and PTA in patients with intermittent claudication is to improve the patients' quality of life and this will be the primary outcome of the study. A difference in improvement has to be demonstrated in the four therapeutic strategies
2. MPWD after six months and one year follow up:
The goal of exercise training and percutaneous transluminal angioplasty is improvement of MPWD. The percentage change in progression of the MPWD will be a primary outcome of this study
3. Costs of therapy:
a. the costs of the different therapeutic strategies will be tracked. Costs of the different therapeutic procedures will be determined with cost-accounting taking into account the investment of equipment in the angiography room and equipment in the vascular laboratory, investments during use, maintenance, years of use, number of procedures per year and personnel costs (specially for hospital-based exercise)
b. the time costs for the patients will be measured by tracking the time patients spend waiting for procedures in the hospital, exercising, and the time during the procedures

Secondary outcome measures

1. Cross-overs from conservative exercise training to revascularisation
2. Cross-overs from revascularisation to conservative exercise training
3. Lifestyle changes (e.g. quit smoking, do more exercise, lose weight)
4. Trend over time in the percentage of eligible patients recruited for randomisation. As long as there is true equipoise with respect to which therapeutic strategy is optimal, both physicians and patients will feel no discomfort with patients being randomised across the four therapeutic work-up strategies. If, over time it becomes clear from clinical experience that using one of the four therapeutic strategies is preferable, physicians will be reluctant to recruit patients for the trial and patients will be unwilling to participate. This should be noticeable in the recruitment rate. Thus, the percentage eligible patients recruited over time will be tracked
5. Event-free survival at six months and one year after randomisation. With an event defined as failure of the exercise programme because of co-morbidities, failure of the PTA procedure, failure to improve symptoms, restenosis, residual stenosis and complications due to the PTA procedure
6. Number of events and all-cause mortality during follow-up
7. ABI in rest and after a treadmill test (after PTA), after six months and after one year follow up
8. Diagnostic imaging of the dilated arterial segment in case of recurrent symptoms

Overall study start date
01/09/2002

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Symptoms of Intermittent Claudication (IC) of at least three months duration
2. Ankle-Brachial Index (ABI) of less than 0.9 in rest or with a decrease in ABI after the treadmill test of more than 30%
3. Symptoms of IC with one or more lesions on imaging work-up at:
a. iliac level suitable for angioplasty (TransAtlantic inter-Society Consensus [TASC] type A, B or C), as agreed upon by the vascular surgeons and interventional radiologists
b. femoro-popliteal level suitable for angioplasty (TASC type A, B or C), as agreed upon by the vascular surgeons and interventional radiologists
4. A MPWD of less than 350m
5. Informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
136

Key exclusion criteria
1. Walking limitations because of co-morbidities, such as angina pectoris, congestive heart failure, chronic obstructive pulmonary disease or arthritis
2. Walking limitations because of immobility, caused by a prior Cardiovascular Accident (CVA) or amputation of a limb
3. Contraindications for the use of iodinated contrast media

Date of first enrolment
01/09/2002

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Ikazia Hospital
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Sponsor information

Organisation
Ikazia Hospital (The Netherlands)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01abkkw91

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2009	20/08/2021	Yes	No