

Comparing Exercise Training and Angioplasty for Claudication: a Randomized Controlled Trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22923

Source

NTR

Brief title

CETAC

Health condition

patients with symptoms of IC stage I-III (Rutherford).

Sponsors and support

Primary sponsor: N/a

Source(s) of monetary or material Support: n/a

Intervention

Outcome measures

Primary outcome

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.

MPWD after 6 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.

Costs of therapy:

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).

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

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 6 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 6 months and after one year follow up;
8. Diagnostic imaging of the dilated arterial segment in case of recurrent symptoms.

Study description

Background summary

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 hospital-based exercise training versus percutaneous transluminal angioplasty in patients with iliac and femoro-popliteal vascular pathology on the quality of life and the functional capacity after 6 months and 12 months follow up.

Study objective

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 6 months and one year follow up.

Study design

N/A

Intervention

Percutaneous transluminal angioplasty:

PTA is an invasive procedure with catheterisation and digital subtraction angiography (DSA). The procedure requires an arterial puncture and a 4-6 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 $< 10-15$ mm Hg), a post-procedural angiography will be performed to show morphologic success. Intra-arterial iodinated contrast is administered through the catheter, as well as heparine.

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 8-10 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.

Contacts

Public

Ikazia Hospital, Department of Surgery,
Montessoriweg 1
S. Spronk
Montessoriweg 1
Rotterdam 3083 AN
The Netherlands
+31 (0)10 2975000

Scientific

Ikazia Hospital, Department of Surgery,
Montessoriweg 1
S. Spronk
Montessoriweg 1
Rotterdam 3083 AN
The Netherlands
+31 (0)10 2975000

Eligibility criteria

Inclusion criteria

Patients with:

1. Symptoms of IC of at least 3 months duration;
2. 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 (TASC (TransAtlantic Inter Society Consensus) 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.

Exclusion criteria

Patients with:

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

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2002
Enrollment:	136
Type:	Actual

Ethics review

Positive opinion	
Date:	09-09-2005
Application type:	First submission

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
NTR-new	NL163
NTR-old	NTR199
Other	: 1361
ISRCTN	ISRCTN64443682

Study results

Summary results

N/A