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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22923

Bron
NTR

Verkorte titel
CETAC

Aandoening

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

Ondersteuning

Primaire sponsor: N/a
Overige ondersteuning: n/a

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2002
Aantal proefpersonen:	136
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL163
NTR-old	NTR199
Ander register	: 1361
ISRCTN	ISRCTN64443682

Resultaten

Samenvatting resultaten
N/A