Exercise therapy with risk factor management and life style coaching after vascular intervention for patients with peripheral arterial disease with critical limb ischemia or tissue loss.

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This pilot study examines the effects of supplementing the standard treatment interventions to improve mobility with modified supervised exercise therapy together with improvements in cardiovascular risk management by using an intensive risk factor...

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

Summary

ID

NL-OMON39070

Source
ToetsingOnline

Brief title
PEARL

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
critical limb ischemia, gangrene

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Life style coaching, Peripheral arterial disease, Risk factor management, Supervised exercise therapy

Outcome measures

Primary outcome

Primary endpoints: pain free and maximum walking distance, quality of life,

illness and pain perception measured with the RAND SF-36, WIQ, and MPQ-DLV.

Secondary outcome

Secondary outcome measures: control of cardiovascular risk factors:

hypertension, diabetes mellitus, hypercholesterolemia. Lifestyle factors:

smoking status, body mass index and waist-hip ratio. Prevalence of confusion

and dementia measured by MMSE and DOS. Functioning on ADL level measured by the

Katz Index. Also registration of mortality and morbidity, vascular

re-interventions, cardiovascular events and hospitalizations and treatments

performed by other specialties. All endpoints measured at baseline, 1, 3, 6, 9

and 12 months.

Study description

Background summary

Supervised exercise therapy is nationally and internationally the treatment of choice for patients with peripheral arterial disease with symptoms of intermittent claudication (Rutherford classification 2-4). This symptomatic treatment is combined with cardiovascular risk factor management. The results

of supervised exercise therapy in this patient population are good. In addition, an increase in quality of life is visible, along with a decrease in medical costs. The nationwide availability of supervised exercise therapy for patients with intermittent claudication has increased since 2003, with reaching a national coverage of trained physiotherapists in 2013 by.
For patients with peripheral arterial disease with symptoms of critical ischemia or limited tissue loss (Rutherford classification 5-6), treatment is primarily aimed at preserving the leg and the function thereof. This combined with the treatment of cardiovascular risk factors, including proper treatment of hypertension, diabetes mellitus and hypercholesterolemia. Estimates of the incidence of critical ischemia range from 0.3 to 1 per 1,000 inhabitants per year, with a prevalence of 0.04 to 0.1%. This patient population is generally much more vulnerable than patients with intermittent claudication and, given the frequent comorbidity result in a high morbidity and mortality. The primary treatment of critical ischemia is in 50% of patients a revascularization, in 25% a primary amputation and 25% pharmaceutical. After only one year 30% has been through an amputation and 25% deceased to predominantly cardiovascular causes.
The 5-year survival of patients with peripheral arterial disease Rutherford 5-6 is 40%. The main variables after an intervention on mortality is not the type of intervention that has been done, or the level of the diseased arterial segment but is determined by the presence of reduced mobility before surgery, not regaining mobility after surgery, loss of autonomy with respect to housing and the presence of dementia.
In the current national and international guidelines for the treatment of patients with Rutherford 5-6, the primary focus is to maintain the affected limb using a vascular intervention, drug treatment and cardiovascular risk factor management. Studies in this patient population on improving mobility with custom supervised exercise therapy, early diagnosis and treatment of dementia and risk factor management with lifestyle coaching were not conducted.

Study objective

This pilot study examines the effects of supplementing the standard treatment interventions to improve mobility with modified supervised exercise therapy together with improvements in cardiovascular risk management by using an intensive risk factor management and lifestyle coaching program supervised by a physiotherapist. The results of this pilot study will be used to develop a multicenter study on the treatment of patients with peripheral arterial disease Rutherford 5-6.

Study design

The treatment of patients in the intervention group consists of several facets: identification of all cardiovascular risk factors and analysis of adequacy of the chosen therapy. If necessary, refer to the vascular physician or family

doctor. Research on degree of confusion and dementia using questionnaires administered by the researcher and this is the case a reference to the geriatric medicine department. After the last clinic visit prior to the scheduled revascularization procedure the patient visits the physiotherapist in the neighbourhood. Participating physiotherapists are all part of ClaudicatioNet. This first session is part of preoperative preparation and lifestyle coaching: the current level of activity, medication use, eating and exercise habits, smoking, pulmonary exercises, physical health and exercise therapy. During the week of hospital discharge after vascular intervention, the patient goes back to the physiotherapist for treatment, if necessary, the physical therapist visits at home. During these sessions, in addition to exercise therapy, attention to lifestyle coaching will be present. Lifestyle coaching includes attention to: medication adherence, stop-smoking counselling, food and weight counselling, and fitness training.

Intervention

The treatment of patients in the intervention group consists of several facets: identification of all cardiovascular risk factors and analysis of adequacy of the chosen therapy. If necessary, refer to the vascular physician or family doctor. Research on degree of confusion and dementia using questionnaires administered by the researcher and if this is the case a reference to the geriatric medicine department. After the last clinic visit prior to the scheduled revascularization procedure physiotherapist visits the patient has been in the neighbourhood.
Participating physiotherapists are all part of ClaudicatioNet. This first session is part of preoperative preparation and lifestyle coaching the following offer: the current level of activity, medication use, eating and exercise habits, smoking, pulmonary exercises, Conditioning and exercise therapy. During the week of hospital discharge after vascular intervention, the patient goes back to the physiotherapist for treatment, if necessary, physical therapist visits the home. During these sessions, in addition to exercise therapy, attention to lifestyle coaching is given. Lifestyle coaching includes attention to: medication adherence, stop-smoking, weight monitoring and fitness training.
Patients in the control group received the current standard treatment. This includes cardiovascular risk management if not previously initiated by a doctor or specialist, oral exercise advice and regular duplex controls. These take place at 1, 3, 6, 9 and 12 months after the intervention.

Study burden and risks

Control and intervention group 10 hours a year basis for completion of the questionnaires. The physiotherapy group receives an average of 2 times per week therapy for a period of one year.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with Rutherford stage 4 and 5 peripheral arterial disease where an open or endovascular intervention is possible to improve the arterial peripheral perfusion.

Exclusion criteria

Servere NYHA 4 comorbidity
Below the knee or above the knee amputation contralateral leg
No physiotherapy coverd in insurance

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	10-08-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	29-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL37122.060.11