Pilot study added value intermittent vacuum therapy (IVT)

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To determine the effect of IVT on walking distance after 6 and 12 weeks, 6 months and 1 year in patients with IC who are treated with a SET program. To determine the optimal timing for IVT within the SET program.

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

Summary

ID

NL-OMON44065

Source
ToetsingOnline

Brief title
Pilot Vacumed

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
intermittent claudication, peripheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: subsidie

Intervention

Keyword: intermittent claudication, intermittent vacuum therapy, peripheral arterial disease, supervised exercise therapy

Outcome measures

Primary outcome

Maximum walking distance after 6 and 12 weeks, 6 months and 1 year, measured by

a standardized treadmill test .

Secondary outcome

Functional walking distance after 6 and 12 weeks, 6 months and 1 year, measured

by a standardized treadmill test .

Quality of life and walking disability after 6 and 12 weeks, 6 months and 1

year, measured by questionnaires.

Study description

Background summary

The preferred treatment for patients with intermittent claudication (IC) is supervised exercise therapy (SET) supported with secondary risk prevention. Today, patients with IC are also treated with intermittent vacuum therapy (IVT). There is no hard evidence supporting the proposed mechanisms of action. If we demonstrate that IVT influences the blood flow restricted by atherosclerosis, it could potentially be an additional treatment for patients with IC.

Study objective

To determine the effect of IVT on walking distance after 6 and 12 weeks, 6 months and 1 year in patients with IC who are treated with a SET program. To determine the optimal timing for IVT within the SET program.

Study design

Randomized, placebo-controlled clinical pilot study of one year in the

Catharina Hospital in Eindhoven, the Maxima Medical Center Veldhoven and the St. Anna Hospital in Geldrop.

Intervention

80 patients divided into 2 groups of 40 patients. Group 1: patients receive a SET program during 1 year supplemented with IVT in weeks 1 till 12. Group 2: patients receive a SET program during 1 year supplemented with sham-IVT in weeks 1 till 12.

Study burden and risks

Patients receive standard conservative management for IC (CVRM and SET) and are also referred to the 'Been-Kliniek' in Eindhoven for IVT or sham-IVT. There is a minimum of 8 and a maximum of 12 IVT or sham-IVT treatments per patient. An IVT or sham-IVT treatment takes 30 minutes. The total time investment per patient is about 6 hours spread over 6 weeks, excluding travel time. There are no risks associated with IVT or sham-IVT.

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

• Conservative treatment with supervised exercise therapy (SET)
• Sufficient additional insurance or sufficient financial resources for a SET program of 1 year
• Sufficiently motivated to participate in the study (particularly additional (travel) time investment for treatment with IVT in the 'Been-Kliniek' in Eindhoven)
• Informed consent

Exclusion criteria

• Previous treatment for PAD in the past 2 years (conservative and/or invasive technique)
• Prior treatment with IVT (possibly for other indications than PAD)
• Cognitive disabilities
• Inadequate control of the Dutch language
• Contraindications for IVT (pregnancy, infection and/or inflammation of the lower limb(s), abdominal wall hernia)
• Recent (<6 weeks) trauma of the lower limb(s)
• Severe cox- or gonarthrosis and planned joint replacement therapy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-12-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	01-12-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-05-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-08-2016
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

ID: 26769
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54340.100.15
OMON	NL-OMON26769