Pilot study added value intermittent vacuum therapy (IVT) in the treatment of intermittent claudication

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26769

Source
Nationaal Trial Register

Brief title
PILOT VACUMED

Health condition

Peripheral arterial disease; Intermittent claudication; Perifeer arteriaal vaatlijden; Claudicatio intermittens

Sponsors and support

Primary sponsor: Catharina Hospital, Eindhoven, the Netherlands
Source(s) of monetary or material Support: Self-financing

Intervention

Outcome measures

Primary outcome

Maximal walking distance, measured by a standardized treadmill test

Secondary outcome

-Functional walking distance, measured by a standardized treadmill test

-Walking distance, measured by a six-minute walk test

-General quality of life, measured by a EQ-5D questionnaire

-Disease-specific quality of life, measured by a VascuQol questionnaire

-Walking impairment, measured by a WIQ questionnaire

Study description

Background summary

The preferred treatment for patients with intermittent claudication (IC) is supervised exercise therapy (SET) supplemented with secondary risk prevention. Since 2015, intermittent vacuum therapy (IVT) is intensively promoted in the Netherlands as a minimally invasive treatment for IC. IVT implies that a patient is placed in a tubular device and undergoes periods of negative pressure applied to the lower body, assumed to stimulate leg circulation. A literature search revealed no hard evidence to substantiate the proposed mechanisms of action. Aim of this multicenter randomized controlled trial is to determine a potentially additional effect of IVT on walking distance and health-related quality of life in patients with IC who are treated with a SET program.

At three vascular surgery outpatients clinics, 80 patients with symptomatic IC, based on a < 0.9 rest ankle-brachial index (ABI) or a > 0.15 ABI drop after exercise, are randomized to two treatment arms of 40 patients. Both groups receive standard conservative management for IC including cardiovascular risk management and a SET program of one year. In addition, the experimental group (“IVT”) receives IVT treatment with a negative pressure of -50 mBar, whereas the control group (“Sham”) receives IVT treatment with a negative pressure of -5 mBar. IVT is provided during twelve 30 minute sessions over a six weeks period. Patients and SET-providing physiotherapists are blinded for the given treatment.

Primary outcome measure is the maximal walking distance (standardized treadmill test). Secondary outcome measures are the functional walking distance (standardized treadmill test), walking distance (six-minute walk test), general quality of life (EQ-5D questionnaire), disease-specific quality of life (VascuQol questionnaire) and walking impairment (WIQ questionnaire). Outcomes are assessed at baseline and after 6 weeks, 3 months, 6 months and 1 year.

Study design

Baseline, 6 weeks, 3 months, 6 months and 1 year

Intervention

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

Contacts

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Eligibility criteria

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)

-Informed consent

Exclusion criteria

-Maximal walking distance >1000 meters at baseline

-Inability to complete 12 IVT sessions in first 12 weeks (vacation)

-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)

-Critical limb ischemia

-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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2015
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-04-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44065
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5987
NTR-old	NTR6353
CCMO	NL54340.100.15
OMON	NL-OMON44065

Study results