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

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| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26769

**Bron**
Nationaal Trial Register

**Verkorte titel**
PILOT VACUMED

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** Catharina Hospital, Eindhoven, the Netherlands
**Overige ondersteuning:** Self-financing

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Maximal walking distance, measured by a standardized treadmill test

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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.

# Contactpersonen

## Publiek

Department of Vascular Surgery
Catharina Hospital

Joep A.W. Teijink
Michelangelolaan 2, 5623 EJ Eindhoven
P.O. Box 1350,

Eindhoven 5602 ZA
The Netherlands
+31 40 2396349

## Wetenschappelijk

Department of Vascular Surgery
Catharina Hospital

Joep A.W. Teijink
Michelangelolaan 2, 5623 EJ Eindhoven
P.O. Box 1350,

Eindhoven 5602 ZA
The Netherlands
+31 40 2396349

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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

## Belangrijkste redenen om niet deel te kunnen nemen

### (Exclusiecriteria)

-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

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Placebo |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-12-2015 |
| Aantal proefpersonen: | 80 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 13-04-2017 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44065
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten