# SUPERvised exercise therapy or immediate PTA for intermittent claudication in patients with an iliac artery obstruction: A randomized controlled trial. SUPER study.

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The purpose of our study is to compare the clinical effectiveness and cost-effectiveness of two treatment strategies of intermittent claudication (IC) due to an iliac artery obstruction: to start with supervised exercise therapy (SET) and deferred…

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

## Samenvatting

### ID

NL-OMON25926

**Bron**
NTR

**Verkorte titel**
SUPER study (NL: SUPER studie)

**Aandoening**

Intermittent Claudication; Claudicatio Intermittens
Supervised Exercise Therapy; gesuperviseerde looptraining
Percutaneous Transluminal Angioplasty; Percutane Transluminale Angioplastiek
Iliac artery obstruction; Arteria Iliaca obstructie

### Ondersteuning

**Primaire sponsor:** Academic Medical Center (AMC)
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**Overige ondersteuning:** ZonMw: The Netherlands Organization for Health Research and Development

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

1. Disease specific Quality of Life (VascuQoL);<br>
2. Maximum Walking Distance (on a standardized treadmill test with a speed of 3.2 km/h at 10% incline after 1 year).

# Toelichting onderzoek

### Achtergrond van het onderzoek

Intermittent Claudication (IC) is a manifestation of cardiovascular disease, reflected by a threefold increased risk in these patients of developing serious cardiovascular events. Treatment of patients with IC is aimed at secondary prevention of cardiovascular events by control of risk factors for atherosclerotic disease, and to improve walking distance and subsequently quality of life. Supervised exercise therapy (SET) and Percutaneous Transluminal Angioplasty (PTA) can effectively improve pain free walking distance, but the optimal choice of treatment, specifically in patients with an iliac artery stenosis or occlusion is unclear. PTA is attractive as initial therapy since PTA of the iliac arteries has an immediate effect and it is durable. There is a lack of evidence from randomized controlled trials (RCT) to define the optimal treatment strategy for patients with IC due to iliac artery lesions; first line treatment with SET and PTA in case of failure, or immediate iliac artery PTA.

Purpose:

To define the optimal treatment strategy of intermittent claudication (IC) due to an iliac artery obstruction: To start with supervised exercise therapy (SET) and deferred percutaneous transluminal angioplasty (PTA) in case of SET failure, or immediate PTA.

Design:

Multicenter randomized controlled trial.

Patients:

400 patients with IC due to an iliac artery stenosis or occlusion.

Interventions:

SET and PTA.

Outcomes:

Primary outcomes are quality of life (Qol) recorded with the disease specific VascuQol instrument and maximum
walking distance on a standardized treadmill test with a speed of 3.2 km/h at 10% incline after 1 year.

Secondary outcomes are pain-free walking distance, generic Qol, functional status, complications, number of treatment failures and costs. Economic evaluation comprises a cost-effectiveness and cost-utility analysis from a societal perspective, with the costs per patient able to walk pain-free, respectively the costs per QALY as outcome measures.

## Doel van het onderzoek

The purpose of our study is to compare the clinical effectiveness and cost-effectiveness of two treatment strategies of intermittent claudication (IC) due to an iliac artery obstruction: to start with supervised exercise therapy (SET) and deferred angioplasty (PTA) in case of SET failure, or immediate PTA.

It is our hypothesis that PTA as first line treatment is more effective than SET as first line treatment with regard to pain free walking distance, quality of life and costs after one year.

## Onderzoeksopzet

1. Baseline;

2. 1, 6, 12 months follow-up.

## Onderzoeksproduct en/of interventie

1. Intervention group: Percutaneous Transluminal Angioplasty;

2. Control group: Supervised Exercise Therapy.

# Contactpersonen

## Publiek

Academisch Medisch Centrum
Afdeling Vaatchirurgie/Interventieradiologie
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## Wetenschappelijk

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# Deelname eisen

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

1. Age 18 years or older;

2. Disabling claudication as defined by surgeon based on patient’s history;

3. Ankle/Brachial Index < 0.9 or drop in ABI > 0.15 after exercise test;

4. Hemodynamic stenosis of the common or external iliac artery on Color Duplex Scanning (PSV ratio ≥ 2.5 or EDV ≥ 0.6 m/s) or on MRA (> 50% stenosis) or occlusion of the common or external iliac artery on Color Duplex Scanning (PSV 0 m/s) or on MRA;

5. Iliac artery lesion and a concomitant stenosis in the superficial femoral artery defined as stenosis > 50% by Color Duplex Scanning (PSV ratio ≥ 2.5 or EDV ≥ 0.6 m/s) or on MRA, or occlusion on DS (PSV 0 m/s) or MRA;

6. Lesion classified A, B or C according to the TASC classification of aorto-iliac lesions;

7. Patient is able to walk at least 2 minutes on a treadmill at 3.2 km/h and 10% incline;

8. The Maximum Walking Distance on a treadmill < 300 meters.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Life expectancy < 3 months;

2. Patient is unable to complete self-reported questionnaires (insufficiently reading or speaking the Dutch language, cognitive disorders, etc);

3. Patient is unable to give informed consent;

4. A documented contrast allergy;

5. Pregnancy;

6. Contra-indication for anticoagulant therapy;

7. Duration of current complaints < 3 months;

8. Occlusion of the common femoral artery at the affected side;

9. Patient participates in another study;

10. Heart failure or Angina Pectoris NYHA III or IV.
(NYHA III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea; NYHA IV: Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased);

11. Patient previously received SET according to KNGF guidelines;

12. Renal insufficiency (serum creatinin > 150 micromol/l).

# Onderzoeksopzet

## Opzet

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

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-11-2010 |
| Aantal proefpersonen: | 400 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 22-02-2011 |
| 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 | NL2648 |
| NTR-old | NTR2776 |
| Ander register | METC AMC/ ZonMw : 09/285 / 171102025; |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A