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

No registrations found.

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

## Summary

### ID

NL-OMON25926

**Source**
Nationaal Trial Register

**Brief title**
SUPER study (NL: SUPER studie)

**Health condition**

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

### Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC)
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**Source(s) of monetary or material Support:** ZonMw: The Netherlands Organization for

Health Research and Development

## Intervention

## Outcome measures

### Primary outcome

1. Disease specific Quality of Life (VascuQoL);

2. Maximum Walking Distance (on a standardized treadmill test with a speed of 3.2 km/h at 10% incline after 1 year).

### Secondary outcome

1. Painfree Walking Distance (on a standardized treadmill test with a speed of 3.2 km/h at 10% incline);

2. Functional Status ( ALDS);

3. Generic Quality of Life ( SF-36 and EQ5D);

4. Complications related to interventions;

5. Treatment failures;

6. Costs.

# Study description

### Background summary

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.

**Study objective**

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.

**Study design**

1. Baseline;

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

**Intervention**

1. Intervention group: Percutaneous Transluminal Angioplasty;

2. Control group: Supervised Exercise Therapy.

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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).

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-11-2010 |
| Enrollment: | 400 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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|---|---|
| Date: | 22-02-2011 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL2648 |
| NTR-old | NTR2776 |
| Other | METC AMC/ ZonMw : 09/285 / 171102025; |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A