# PETRI: Prehabilitation in the Elderly with chronic limb Threatening Ischemia

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON28123

**Source**
Nationaal Trial Register

**Brief title**
PETRI

**Health condition**

Chronic Limb Threatening Ischemia (CLTI)

### Sponsors and support

**Primary sponsor:** Prof. dr. L. van der Laan
**Source(s) of monetary or material Support:** None yet. Conceivably: Amphia academy Science fund

### Intervention

### Outcome measures

**Primary outcome**

Postoperative delirium

**Secondary outcome**

Secondary outcomes will be in-hospital mortality, 30 day, 6 month and 12 month mortality, complications, rates of major amputations, amputation free survival (AFS), length of hospital stay, Quality of Life (QoL, measured by using the WHOQOL-BREF, SF-12 and VascuQoL-6-NL), functional outcome, cognitive function and biochemistry.

# Study description

### Background summary

The primary aim of our study is to reduce the incidence of delirium among patients >65 years with chronic limb threatening ischemia, requiring revascularization by implementing a multicomponent multidisciplinary prehabilitation program.

### Study objective

Our hypothesis is that by implementing the prehabilitation program, the rate of delirium will be decreased from 18% to 9%.

### Study design

Preoperative, admission, 6 months, 12 months

### Intervention

Prehabilitation program. Participants will be screened by a nurse practitioner, physiotherapist and dietician. In case of criteria for frailty (as described in ‘appendix’), a geriatrician will perform a comprehensive geriatric assessment (CGA). Depending on this baseline analysis, patients may receive iron infusion and/or vitamin supplementation, recommendations concerning daily exercise and dietary supplements and guidance in reducing alcohol and/or nicotine use. They are asked to keep track of their activities in a daily diary

# Contacts

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# Eligibility criteria

## Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Aged 65 years or older
- All genders
- All ethnicities
- Diagnosis of CLTI (Chronic Limb Threatening Ischemia), based on either:
o Anamnestic complaints of ischemic rest pain or night pain
o (Minor) tissue loss, non-healing ulcer and/or focal gangrene with diffuse pedal ischemia[11]
o Impaired perfusion, quantified by a flat or barely pulsatile ankle or metatarsal PVR (pulse volume recording), a low resting ankle pressure, a low ankle brachial index and/or a low toe pressure.
- Indication and informed consent to undergo either endovascular or surgical treatment
- No need to start treatment earlier then 3 weeks, counting from the moment of diagnosis

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Dementia according to DSM-V
- Inability to complete questionnaires, due to either lingual or cognitive incompetence.
- Need for urgent surgery (<3 weeks)

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2021 |
| Enrollment: | 170 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Yes

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 29-03-2021 |
| 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 | NL9380 |
| Other | MEC-U : W21.061 |

## Study results