

# Critical Limb Ischemia: Perfusion Computed Tomography.

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|------------------------------|-----------------------------|
| <b>Ethical review</b>        | Approved WMO                |
| <b>Status</b>                | Recruitment stopped         |
| <b>Health condition type</b> | Skin vascular abnormalities |
| <b>Study type</b>            | Observational invasive      |

## Summary

### ID

NL-OMON40070

### Source

ToetsingOnline

### Brief title

CLIP-CT

### Condition

- Skin vascular abnormalities
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

### Synonym

peripheral vascular disease and atherosclerosis of the lower limb

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Computed tomography, Critical limb ischemia, Perfusion

## Outcome measures

### Primary outcome

- Signal/contrast to noise ratio of the PCT scans
- PCT imaging quality scores
- PCT perfusion values (blood volume, blood flow, time to peak and mean transit time) of different predefined regions of the ischemic and non-ischemic foot
- Pedal arterial patency based on DSA

### Secondary outcome

No secondary study parameters/outcomes

## Study description

### Background summary

Critical limb ischemia (CLI) is a severe symptom of peripheral arterial disease (PAD) and is characterized by ischemic pain at rest or non-healing ischemic ulcers or gangrene in the lower extremity. Revascularization of the limb is currently the only intervention which can achieve limb salvage. However, selecting patients who will benefit from revascularization based on current imaging modalities remains challenging. Therefore, imaging techniques to assess the microvascular status of the lower limb are needed. Perfusion CT may be a good technique to assess the microvascular status, as this modality has already showed its usefulness in the field of neurology in patients with ischemic stroke.

### Study objective

The main objective of this study is to assess perfusion of the foot and correlate perfusion values with arterial patency. To this end, first the PCT protocol of the foot in patients with CLI needs to be optimized in terms of contrast dose administration (volume, concentration and rate of administration)

and imaging quality.

## Study design

This will be a bipartite prospective study including 18 patients in total. The first 8 patients will be studied to optimize the contrast injection protocol of PCT, the next ten patients will be evaluated to assess perfusion values and correlate these to digital subtraction angiography (DSA).

## Study burden and risks

There are no benefits for the patients participating in this study. Patients undergo a CT procedure with administration of iodinated contrast. Next to the risk of the radiation from the CT, the contrast material brings a risk for contrast-induced nephropathy or allergic reaction. The health risk from this radiation in this population is graded as a \*minor risk\*, since the effective dose will be around 0.4 mSv per patient. The risk for contrast-induced nephropathy is mainly applicable to patients with chronic renal failure, who are excluded from this study.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- rest pain, nonhealing ulceration or gangrene of the foot, i.e. Fontaine III/IV
- ankle-brachial pressure index (ABPI) < 0.7 or toe pressure < 50 mmHg
- critical limb ischemia > 2 weeks
- normal renal function (i.e. creatinine <130\* $\mu$ mol/l)
- written informed consent

### Exclusion criteria

- inability to give informed consent
- contraindications for contrast-enhanced CT, i.e. allergic reactions to iodinated contrast agents or pregnancy
- major amputation; amputation above the level of the ankle
- patient participates in another study

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 05-04-2013

Enrollment: 18

Type: Actual

## Ethics review

Approved WMO

Date: 04-01-2013

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 18-10-2013

Application type: Amendment

Review commission: METC Amsterdam UMC

## 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             |
|----------|----------------|
| CCMO     | NL42541.018.12 |