Critical Limb Ischemia: Perfusion Computed Tomography.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin vascular abnormalities
Study type	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 secundary 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

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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*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