Prospective Registration Of Critical Leg Ischemia Outcomes in the Netherlands

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To assess the effectiveness of treatment of patients with CLI comparing best supportive care and best supportive care with surgical or endovascular revascularization. This in order to identify patientgroups in which an intervention may not be...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON48610

Source
ToetsingOnline

Brief title
PROCLION

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
peripheral arterial disease, peripheral vascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Critical ischemia, Peripheral arterial disease, Quality of life, Treatment

Outcome measures

Primary outcome

The primary endpoints are amputation free survival (AFS) and patient reported outcomes measures (PROMS) after 12 months follow-up.

Secondary outcome

* Wound healing (complete epithelialization)

* Overall survival

* Limb salvage

* Major amputation (proximal to the level of the ankle)

* Minor amputation (toe, forefoot)

* Resource utilization (outpatient visits, need for rehabilitation, nursing home care).

* Events (reinterventions, readmissions)

* Cost of care within 12 months

Study description

Background summary

Critical limb ischemia (CLI) is an advanced stage of peripheral arterial disease of the lower extremity, characterized by ischemic pain, gangrene or tissue loss, which carries a high risk of amputation. In addition, patients with CLI have a poor overall prognosis due to advanced age and comorbidities. Treatment of CLI consists of antibiotics, wound debridement and endovascular or surgical revascularization. However, revascularization is probably not necessary for a substantial number of patients for limb salvage, pain relief, wound healing and to improve quality of life, but are certainly more costly and

burdensome than the non-interventional option.

Study objective

To assess the effectiveness of treatment of patients with CLI comparing best supportive care and best supportive care with surgical or endovascular revascularization. This in order to identify patientgroups in which an intervention may not be necessary.

Study design

Prospective observational multicenter cohort study with 12 months of follow-up.

Study burden and risks

Not applicable

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

Critical limb ischemia is defined as following;
Patients must have ischemic rest pain, tissue loss, ulcer or gangrene. Symptoms have to be present for more than two weeks at time of enrollment. PAD must be confirmed by one of the following;
* Absolute systolic ankle pressure < 70 mmHg
* Systolic Toe Pressure < 50 mmHg
* Transcutaneous oxygen pressure (tcPO2) < 50 mmHg
* One or more significant (>50%) obstructions in the iliac or lower limb arteries as found with non-invasive imaging (duplex ultrasonography (DUS), Magnetic Resonance Angiography (MRA), Computed Tomography Angiography (CTA)) or digital subtraction angiography (DSA)
* Written informed consent

Exclusion criteria

In the case of meeting any of the following criteria patients will be excluded from enrollment.
* Acute ischemia; due to emboli or trauma
* Non-atherosclerotic origin of ischemia; arteritis, thrombangitis obliterans (Buerger*s disease)
* Hypercoagulable states
* Venous ulcer
* Insufficient proficiency of Dutch language, or inability to complete the Dutch questionnaires
* In the case of bilateral affected limbs, the least affected limb will be excluded.
* Ipsilateral peripheral revascularization intervention of the affected limb within the last three months before presentation

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2017
Enrollment:	502
Type:	Actual

Ethics review

Approved WMO Date:	30-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2019
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2019
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	NL62489.018.17
Other	Wordt geregistreerd onder NCT, NRT nummer volgt