Follow-Up after Revascularization using Laser Speckle Contrast Imaging & transcutaneous oxygen pressure - A multicenter Trial

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Assess the predictive capabilities of LSCI on the effect of endovascular revascularization on the microcirculation of the feet over time and what could this mean for clinical decision-making.

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

Summary

ID

NL-OMON53252

Source
ToetsingOnline

Brief title
FoRever

Condition

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

Synonym
chronic limb threatening ischemia, chronic oxygen deficiency in the leg vessels

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diabetic foot, LSCI, Revascularization, TcPO2

Outcome measures

Primary outcome

LSCI (Perfusion Units) at specific regions or over time.

Oxygen (TcPO2) pressure in mmHg per measurement location and over time

Clinical outcome using multiple parameters derived from the patient files, such as wound healing (time to), successful revascularization (based on DSA), ankle brachial index, toe pressure, amputation yes/no, wound status (WiFi classification) and VAS score

Secondary outcome

Objective 1,2 and 3, are needed to answer the main objective and therefore use the same parameters. Objective 4 will use additional regions of interest (measured in Perfusion Units) to determine the distribution of LSCI perfusion units in the presence of an ulcer.

Study description

Background summary

In patients with chronic limb threatening ischemia (CLTI), often associated with Diabetes Mellitus (DM), an insufficient blood supply will result in ischemic restpain, or wounds that heal slowly or not at all. To enable wound healing a revascularization procedure is needed, where an endovascular approach is often the preferred treatment. Currently, there is no sufficient technique

to determine the severity of (local) ischemia. Laser speckle contrast imaging is a technique that can image the microcirculation, measuring the superficial blood flow in tissue and the wound, giving more insights into (local) ischemia. Transcutaneous oxygen pressure (TcPO2) is a measurement to measure the oxygenation status at a single point on the skin. Using this study, we want to gain more insight in how and especially when both techniques can be used, so that caretakers can act based on these measurements and prevent ulcers or even amputations.

Study objective

Assess the predictive capabilities of LSCI on the effect of endovascular revascularization on the microcirculation of the feet over time and what could this mean for clinical decision-making.

Study design

Multicentre observational cohort study.

Study burden and risks

Measurements will be performed during regular appointments at the outpatient clinic. Due to the non-invasive nature of this study, there is no burden or risk associated with participation. The measurements during the five study visits take approximately 20 minutes each time. So there is a time burden.

Contacts

Public
Ziekenhuisgroep Twente

Zilvermeeuw 1
Almelo 7609PP
NL
Scientific
Ziekenhuisgroep Twente

Zilvermeeuw 1
Almelo 7609PP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with ischemic foot ulcers
>=18 years of age
Planned to receive revascularization treatment by standard care practice protocol.
Willing to give written informed consent and willing and able to comply with the study protocol
Fontaine 3 and 4

Exclusion criteria

- Patients with contact restrictions.
- Forefoot amputation or larger
- Patients with large wounds or severe gangrene will be excluded when this would make applying the TcPO2 suction cups impossible.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2024
Enrollment:	152
Type:	Actual

Ethics review

Approved WMO Date:	31-08-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-01-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-10-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL84057.100.23