Near-infrared fluorescence with indocyanine green for intra-procedural assessment of foot perfusion following endovascular revascularization

Published: 12-06-2024
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The primary objective is to investigate the feasibility of NIR fluorescence imaging with intra-arterial ICG to detect differences in foot perfusion following successful endovascular lower extremity revascularization.

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

Summary

ID

NL-OMON56820

Source
ToetsingOnline

Brief title
INFLOW

Condition

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

Synonym
blood flow of lower leg, Lower extremity tissue perfusion

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Health Holland - Public Private Partnership grant

Intervention

Keyword: Endovascular revascularisation, Fluorescence imaging, Indocyanine green, Perfusion

Outcome measures

Primary outcome

The main outcome parameter is the difference between quantified fluorescence in

the foot, before - and after the endovascular intervention.

Secondary outcome

- usability score of the technique by vascular surgeon or interventional

radiologist

- correlation between quantified fluorescence parameters, judged effect by

angiography and duplex ultrasound measurement

Study description

Background summary

Lower extremity arterial disease (LEAD) is caused by atherosclerosis in the lower limb, leading to symptoms varying from claudication to ulcer formation. For patients with advanced stages of LEAD (i.e. wounds or rest pain), a revascularization procedure is often needed to obtain limb salvage, which is increasingly being performed with an endovascular intervention. However, diagnostic methods describing the actual increase in perfusion skin level remain unknown. Especially for patients with wounds, information about the increase in perfusion following revascularization might guide revascularization strategies. Near-infrared fluorescence imaging with intra-arterial indocyanine green (ICG) has the potential to fill this diagnostic gap of perfusion

assessment.

Study objective

The primary objective is to investigate the feasibility of NIR fluorescence imaging with intra-arterial ICG to detect differences in foot perfusion following successful endovascular lower extremity revascularization.

Study design

A single center prospective feasibility study.

Study burden and risks

The risk associated with participation are primarily the (very low) risks of adverse reactions due to the administration of ICG. Intravenous ICG has been safely used for over 60 years for different indications. Since the dosage used in this study is significantly less than the intravenous dosage (1/10), no additional risk is expected. Patients meeting one or more of the contraindications for ICG are excluded from this study. No extra blood samples, physical examinations, questionnaires or other tests will take place.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Adult (>18 years).
2. Rest pain or wounds due to LEAD
3. Scheduled for lower extremity endovascular revascularization.
4. Able to understand the information and implication of participation in the study.

Exclusion criteria

1. Allergy to ICG, iodine or sodium iodide.
2. Allergy to shellfish.
3. Hyperthyroidism.
4. Autonomous thyroid adenoma.
5. Previous hypersensitivity to ICG.
6. Pregnancy or breastfeeding.
7 Kidney failure (eGFR <10 ml/min/1.73m2).
8. Any condition that the investigator considers to be potentially jeopardizing the patient*s well-being or the study objectives.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-08-2024
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	12-06-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-09-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL85774.058.23