

# Anatomical mapping and evaluation of skin-tissue perfusion using Indocyanine green near-infrared fluorescence (ICG-NIR) in patients with peripheral arterial disease.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON24639

### Source

NTR

### Health condition

Peripheral arterial disease

## Sponsors and support

**Primary sponsor:** LUMC

**Source(s) of monetary or material Support:** LUMC, vascular surgery department

## Intervention

## Outcome measures

### Primary outcome

Peripheral tissue perfusion expressed in drainage ratio of ICG. Drainage ratio is calculated by the fluorescence intensity value 5 minutes after ICG injection divided by the maximal

fluorescence value multiplied by 100. We will also measure the T<sub>max</sub>, T<sub>1/2</sub> and FT<sub>10</sub> (fluorescence intensity value 10 seconds after injection).

## Secondary outcome

Correlation between NIR-fluorescence with conventional imaging modalities. To each patient we will measure ankle brachial index and toe pressures. Also, we will compare CT-angiography images with NIR-fluorescence images in patients who have had a CTA within 1 year before present study.

# Study description

## Background summary

Atherosclerosis in major (peripheral) vessels and the subsequent decreased arterial perfusion of extremities can cause ischemic pain, ischemic ulcers and can eventually lead to amputation. At present, Computed Tomography Angiography (CT-A) and X-ray contrast angiography (XA) are the most sensitive diagnostic modalities regarding PAD. While both are well able to diagnose macrovascular occlusive pathologies they lack the ability to adequately assess microvascular (skin) perfusion. This researchproject's focus is to bridge this gap using a promising new diagnostic instrument: NIR fluorescence imaging.

## Study objective

Is indocyanine green near infrared fluorescence imaging, using a handheld camera system, able to accurately evaluate and quantify the peripheral tissue perfusion in patients with peripheral arterial disease?

Hypothetically, as indocyanine green goes through microcirculation, and the drainage of ICG is constantly measured by the NIR light camera, the actual tissue perfusion can be accurately quantified in a non-invasive way.

## Study design

Inclusion active

# Contacts

## Public

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**Scientific**

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## Eligibility criteria

### Inclusion criteria

Patients diagnosed with peripheral arterial disease(PAD).

Patients planned for percutaneous transluminal angioplasty as a treatment for PAD

Patients planned for bypass surgery as a treatment for PAD

Patients planned for an amputation of a (part of) lower extremity as a treatment for PAD Age  
18-80 years old

### Exclusion criteria

Allergy or hypersensitivity for natriumiodide, iodium or indocyanine green

Hyperthyroidism or autonomous thyroid adenoma

Pregnancy

Severely impaired liver function

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL

Recruitment status: Recruiting  
Start date (anticipated): 13-01-2019  
Enrollment: 70  
Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion  
Date: 19-02-2019  
Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 55609  
Bron: ToetsingOnline  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL7531
CCMO	NL65455.058.18
OMON	NL-OMON55609

## Study results