

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.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	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 Tmax, T1/2 and FT10 (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

LUMC

Pim van den Hoven

+31645036309

Scientific

LUMC

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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, iodine 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