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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24639

Bron
NTR

Aandoening

Peripheral arterial disease

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: LUMC, vascular surgery department

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Inclusion active

Contactpersonen

Publiek

LUMC
Pim van den Hoven

+31645036309

Wetenschappelijk

LUMC
Pim van den Hoven

+31645036309

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Allergy or hypersensitivity for natriumiodide, iodium or indocyanine green
Hyperthyroidism or autonomous thyroid adenoma
Pregnancy
Severely impaired liver function

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-01-2019
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55609
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten