Anatomical mapping and assessment of tissue perfusion using indocyanine green near-infrared fluorescence in patients with peripheral arterial disease.

Published: 12-12-2018
Last updated: 15-05-2024

The main objective of this study is to asses the applicability and validity of ICG parameters in the diagnostic work-up in patients with peripheral arterial disease. We will also asses the applicability of ICG-NIRF in intra-operative assessment of...

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

Summary

ID

NL-OMON55609

Source
ToetsingOnline

Brief title
ICG-NIRF in peripheral vascular disease

Condition

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

Synonym
claudication, peripheral occlusive disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Indocyanine green (ICG), Near-infrared fluorescence (NIRF), Peripheral vascular disease

Outcome measures

Primary outcome

primairy outcome:

Peripheral tissue perfusion of the lower limb expressed in drainage ratio:

Drainage ratio = (fluorescence on 5 min after injection/maximum fluorescence) *

100

Secondary outcome

none

Study description

Background summary

Peripheral arterial disease (PAD) is a common and potential life-threatening disease, mainly caused by atherosclerotic
disease.In case of severe PAD, revascularization therapy is frequently necessary and can even lead to amputation in
some cases. Present-day conventional diagnostics might give an estimate of macrovascular deviations but is not
accurate enough to asses tissue perfusion in the end-organ. In some patient populations conventional diagnostics can
be fasely elevated or can not be measured when previous amputation is performed. Therefore a dynamic, accurate
and non-invasive diagnostics modality for the assesment of tissueperfusion is necessary. Indocyanine green NIRF is
considerd a potentional modality for accurate tissueperfusíon imaging used for PAD diagnostics and in the prediction of

patency after revascularization and potential woundhealing.

Study objective

The main objective of this study is to asses the applicability and validity of ICG parameters in the diagnostic work-up in patients with peripheral arterial disease. We will also asses the applicability of ICG-NIRF in intra-operative assessment of the level of amputation.

Study design

A phase II single centre study. Patients will be divided into 4 groups (including one controlgroup with healthy participants).All patients will receive a dosis of ICG based upon weight (0.10 mg/kg) before NIRF measurements.
in the first and second group NIRF imaging will be done both before and after non-/invasive therapy. In the amputation group NIRF imaging will be done before, during and 3 days after amputation. The control group wil undergo NIRF imaging once. This group will not receive an extra dosis of ICG. We will only place the fluorescence camera above the feet during or right before the operation for which they will already receive a dosis of ICG.

Study burden and risks

Burden:
- On the day of NIRF imaging ICG (0.10 mg/kg) will be administered intravenously.
- therefor an iv must be placed before every ICG-NIRF measurement (minimum of 1 till maximum of 3 times over a period of 6-7 months).
- NIRF imaging takes about 30 minutes in total. the patient must lay or be positioned in a semi-seating position for a maximum of 15 minutes).

No additional visits tot the outpatient clinic are necessary.
After the NIRF-measurements are finished the patient can leave the hospital.

Risks:
The risk is estimated as a mediocre risk, this is due to the fact that a body foreign solution is administered. There is extensive knowledge and experience with the administration and use of ICG and NIRF within LUMC hospital.
ICG administration has a very low risk of adverse events wherefore treatment is necessary (0.05-0.07%).

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years or older
- patients with peripheral vascular disease catagorized wit at least fontaine 2A classification
- Abscence of any psychological, familial, sociological or geographical condition potentially hampering
compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.
- Before patient registration, written consent must be given according to ICH/GCP, national and local
regulations.

Exclusion criteria

- hisory of allergy to iodine, shellfish or ICG
- patients with hyperthyroidism
- pregnant or lactating woman
- any condition that in the opinion of the investigator could potentially jeopardize the health status of the patient.
- patients with severe liver failure

Study design

Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-02-2019
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-02-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	22-02-2021
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

ID: 24639
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65455.058.18
OMON	NL-OMON24639