ArteriaL Fluorescence Angiography for Peripheral Arterial Disease (ALFAPAD) Study

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Primary Objective: 1. To determine the feasibility and clinical relevance of quantifiable parameters from intraoperative ALFA-measurements. Secondary Objective(s): 1. Determine the intraoperative applicability of ALFA. 2. Determine the effect of...

Ethical review	Approved WMO
Status	Completed
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON53719

Source
ToetsingOnline

Brief title
ALFAPAD

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
peripheral arterial disease; atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Medisch Spectrum Twente

Intervention

Keyword: Fluorescence angiography, Indocyanine Green, Peripheral arterial disease

Outcome measures

Primary outcome

1. Near-infrared video-data and the quantified parameters based on

intensity-time curves of ALFA measurements.

2. Clinical improvement; wound healing (WIFI classification, amputation and

walking distance (Rutherford classification) after 6 months.

Secondary outcome

1. Technical success of ALFA measurements.

2. Technical success of the PAD treatment procedure.

3. Quantified parameters extracted from postoperative intravenous FA

measurements.

4. Number of adverse events.

Study description

Background summary

In Peripheral Arterial Disease (PAD), macrovascular lesions cause a change in haemodynamics in the lower limbs, reducing distal perfusion pressure. The microcirculation and nutrient blood flow to tissue becomes severely impaired, ultimately resulting in critical limb ischemia (CLI) and accompanying symptoms such as ischemic rest pain or non-healing wounds. For patients with CLI, the prognosis of the leg is strongly limited unless successful revascularization is

performed. In most cases, the first choice of invasive treatment is Percutaneous Transluminal Angioplasty (PTA), possibly supplemented with the placement of a stent. The currently employed imaging techniques are not applicable for assessment of the microcirculation in the foot, even though the procedure is aimed at improving this very matter. A second imaging/assessment module should be introduced that can visualise the microcirculation of the foot. It should be able to assess the effect of the endovascular treatment during the procedure and eventually predict clinical outcome.

In this study, fluorescence angiography (FA) will be used to assess the perfusion of the plantar side of the foot. FA uses near-infrared light in combination with a fluorescent dye, indocyanine green (ICG), to image blood flow in tissue. During FA, ICG is generally administered intravenously. The endovascular sheath used during PTA, however, allows an alternative arterial injection (ALFA), which should theoretically lead to improved images with greater discriminatory power and higher repeatability.
The rationale of this research is to determine whether peroperative ALFA can be used to objectively measure perfusion and tissue characteristics during a revascularization procedure. This pilot study should indicate whether further investigations are meaningful, and how quantitative analysis of ALFA images should be performed.

Study objective

Primary Objective:
1. To determine the feasibility and clinical relevance of quantifiable parameters from intraoperative ALFA-measurements.

Secondary Objective(s):
1. Determine the intraoperative applicability of ALFA.
2. Determine the effect of revascularization on the defined parameters.
3. Determine the ability of these parameters to predict clinical outcome.
4. Determine the added value of post-operative intravenous FA measurements, as well as their relation to intraoperative ALFA.

Study design

This pilot study will be organised as a prospective observational surgeon-blinded single centre (MST Enschede) cohort study. In this case, surgeon-blinded means that the operating surgeon cannot observe the ALFA images, to ensure that they do not alter their operative strategy based on this study.

Patients will undergo the following course of actions:
1. In the outpatient clinic, after having agreed to perform surgery based on shared decision-making, the surgeon will provide information (including PIF) on

the study and asks whether the patient would be willing to participate. While patients are free to formally decline at this point, agreement will be noted as *preliminary*.
2. The evening/morning before the surgery, the clinical researcher will formalize the patient*s agreement to participate by gaining written informed consent.
3. During the operation, ALFA measurements by intra-arterial administration of ICG (0.01 mg/kg bodyweight) will be performed twice in a standardized fashion. The first occurs after general anaesthesia has been administered and the endovascular sheath has been established according to the normal operative plan. The second measurement will be performed after the surgeon either finishes or aborts the procedure. The increased duration of the entire operation is estimated at approximately 2 x 5 = 10 minutes.
4. The day after surgery, patients will undergo a *regular* intravenous FA measurement (5mg ICG) at the nursing ward. The aim of this is to relate these measurements to intraoperative ALFA measurements and to investigate the use of intravenous FA as an imaging tool to be used in clinical follow-up. To this end, the standard dosage of 5mg ICG will be injected through a readily present intravenous catheter.
5. Regular follow-up at nursing ward and outpatient clinic, according to standard-of-care. Clinical parameters will be extracted from medical records.

Study burden and risks

Leaflet of Verdye: ICG has a very low risk profile, with anaphylactic reactions < 0.01%. Patients with a known increased risk for adverse events as mentioned in the leaflet will not be included in this study.

Near-infrared imaging using LED is non-ionizing, non-contact and completely unharmful for patients and users without the need for protective measures. Users are educated by Karl Storz on the use of the system.

This study is observational and surgeon-blinded, so there are no potential benefits or risks to be had in regard to operative strategy or clinical outcome.

Contacts

Public
Medisch Spectrum Twente

Koningsplein 1
Enschede 7512 KZ

NL
Scientific
Medisch Spectrum Twente

Koningsplein 1
Enschede 7512 KZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Peripheral arterial disease patients with a Rutherford classification of 4, 5 or 6

Exclusion criteria

Severely impaired renal function (eGFR < 30 ml/min)
Known allergy or hypersensitivity for iodine
Hyperthyroidism

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-02-2024
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	18-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL83106.100.23