Reproducibility and rEliability of Perfusion angiography and prEdiction of wound heAling in criTical limb ischemia.

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

Summary

ID

NL-OMON43228

Source
ToetsingOnline

Brief title
REPEAT study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Critical limb Ischemia; vascular obstructions with rest pain and non healing wounds

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: angiography, critical, ischemia, perfusion

Outcome measures

Primary outcome

• Reproducibility and inter-rater reliability of PA

• Correlation between DSA and PA and wound healing at 3 months

Secondary outcome

• Correlation between DSA and PA and wound healing at 6 months

• To gain insights in the flow dynamics during revascularization procedures

Study description

Background summary

Critical limb ischemia (CLI) is a serious condition caused by end stage peripheral artery disease (PAD) in which the viability of the lower extremity is at risk. The aim of CLI treatment is optimization of inflow to the diseased part of the lower extremity. This can be achieved by open bypass surgery or in an endovascular fashion. Unfortunately, the success of endovascular revascularization is largely unpredictable as demonstrated by a high rate of failed or delayed wound healing and repeat interventions. Non-invasive measurements such as toe pressures, TcpO2 or near-infrared spectroscopy (NIRS) can be helpful but do not correlate well with wound healing and are generally not available intra-procedurally. Currently, the operators rely largely on their own experience and *eyeball* the results of their revascularization efforts by looking at the flow through the arteries below the knee (BTK), the pedal arteries, and wound blush using iodinated contrast injected into the arteries and imaged using X-ray.

Philips has developed a tool in order to provide quantitative interpretations of the images, and thereby assist in the objective intra-procedural evaluation of revascularization. The tool, referred to as *2D Perfusion* (2DP) is commercially available, and functions by extracting flow information from the X-ray images. A protocol for the use of 2DP in CLI patients has been developed and early results suggest that the extent of increased blood flow to the foot can be determined. However, these results should be interpreted with some

thought because data on reproducibility and reliability in CLI are missing. If reproducibility and reliability of PA are good this technique may provide per procedural information about the target vessels that need to be re-vascularized to obtain good inflow to the ischemic part of the foot and may determine a metric above which clinical outcomes are typically favorable.

Study objective

The objective of this study is twofold. First objective is to determine the reproducibility and inter-rater reliability of Perfusion Angiography. The second is to investigate the predictive value of Perfusion Angiography for wound healing in Critical Limb Ischemia.

Study design

This is a single centre pilot study with a prospective observational character carried out in the St. Antonius Hospital. Operators will be blinded for the perfusion results during the procedure to prevent treatment bias.

Study burden and risks

There will be no direct benefit for subjects participating in this study. The risk associated with participation are related to the use of extra contrast material and radiation dose.

Risks associated with additional contrast medium.
Subjects with CLI are generally at a higher risk of developing contrast-induced acute kidney injury (CI-AKI). To minimize this risk subjects with an eGFR <30 will be excluded from this study and the amount of contrast will be limited to a maximum of 40 mg Iodine or 150 mL of Visipaque 320 (GE Healthcare Inc.). Furthermore, the protocol used in this study to prevent CI-AKI is in line with the local hospital doQu guidelines. A recent study showed no difference between intravenous or intra-arterial contrast administration with respect to the occurrence of CI-AKI.

Risks associated with additional radiation dose.
To check if the use of extra radiation dose is justifiable the guidelines of the Netherlands Commission on Radiation Dosimetry May 2016 were used. The maximum extra radiation dose in this study is 5.6 Gycm2. To calculate the effective dose as a rule of thumb, this number of corresponds to an extra radiation dose of 0.23*5.6 = 1.3 mSv.
Taken into account that subjects in this study are generally older than 50 years of age the additional effective dose can be divided by 5-10. This means that these subjects in this study are in ICRD risk category IIA. Subjects younger than 50 years of age will be in category IIB.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• diagnosed with CLI according to the TASC II Working Group criteria
• present with non-healing ulcers or gangrene (RB 5-6)
• older than 18 years
• no or adequately treated inflow disease

Exclusion criteria

• severe renal failure defined as an eGFR <30 mL/1.73 m2
• severe allergy to contrast medium resulting in an absolute contra-indication for administration
• pregnancy

• scheduled or anticipated major amputation (above the ankle)
• inability to position the foot in the footrest used for PA
• inability to give informed consent
• Distal embolization after treatment of inflow vessels

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-12-2019
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

ID: 25243
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59437.100.16
OMON	NL-OMON25243