The Use of Intravascular Ultrasound (IVUS) in Below-The-Knee (BTK) Arteries: A Randomized Controlled Trial.

Published: 28-02-2024
Last updated: 07-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON56490

Source
ToetsingOnline

Brief title
TIBA

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Critical Limb Ischemia (CLI), narrowed arteries

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Onderzoeksfonds St. Antonius Ziekenhuis

Intervention

Keyword: endovascular revascularisation, infrapopliteal, intravascular ultrasound, percutaneous transluminal angioplasty

Outcome measures

Primary outcome

The primary endpoint is NLG following IVUS-guided intervention when compared

with angiography-guided intervention after six weeks.

Secondary outcome

Secondary endpoints include ALG and per-procedural complications such as

arterial dissections.

Study description

Background summary

Endovascular interventions of below-the-knee (BTK) arteries are vital for limb salvage in patients with chronic limb threatening ischemia (CLTI). Unfortunately, endovascular treatment of BTK arteries has dissapointing results in terms of patency. One of the reasons may be insufficient imaging of these diseased arteries during the procedure with fluoroscopy and angiography. As angiography shows a longitudinal two-dimensional image of the artery, it is only capable of showing the vessel lumen, thereby the choice of accurate treatment method and balloon sizing are challenging. Furthermore, complications such as dissections may go unnoticed on angiography. In contrast, intravascular ultrasound (IVUS) shows a cross-sectional image of the target lesion and vessel lumen with improved detection of complications. Combining both angiography and IVUS gives a three-dimensional impression of the target lesion and artery. This improved imaging may lead to more accurate endovascular intervention methods, potentially resulting in an increase in acute lumen gain (ALG), an increase in net lumen gain (NLG) and subsequently better outcomes. In addition, IVUS may lead to improved detection of immediate post-procedure complications.

Study objective

The main objective is to investigate whether the additional use of IVUS leads to an increase in net lumen gain (NLG) when compared with standard

angiography-guided endovascular treatment as measured during control IVUS after six weeks. Secondary objectives are related to per-procedural complications.

Study design

Monocenter investigator-initiated single-blind randomized controlled trial.

Intervention

IVUS-guided endovascular intervention of BTK arteries.

Study burden and risks

During endovascular treatment, IVUS will be used in addition to angiography to guide the endovascular intervention and measure the vessel diameter. The insertion of an IVUS catheter has no specific risk of complications. Balloon sizing with the aid of IVUS will most likely lead to the use of larger balloons. These balloons may cause more severe dissections or perprocedural pain. On the other hand, the potential increased ALG and NLG at six week may lead to faster wound healing and decreased risk of lower limb amputation.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age >18 years old;
* CLTI, defined as the presence of PAD in combination with rest pain, gangrene, or a lower limb ulceration >2 weeks duration;
* Indication for BTK endovascular revascularization, as set by the multidisciplinary team;
* De novo vascular target lesion;
* Written informed consent.

Exclusion criteria

* Target lesions with a length of <5 cm or >20 cm;
* Kawarada Type III pedal arch (no patent dorsalis pedis artery, no patent plantar artery);
* Below-the-knee (BTK) critical limb ischemia (CLTI) based on acute thrombosis or thrombo-emboli;
* Renal insufficiency with a glomerular filtration rate (GFR) of less than 15 ml/min but not on dialysis;
* Contrast allergy;
* Non-salvageable limbs due to extensive tissue necrosis or infection (Rutherford classification of chronic limb ischemia 6 or WiFi classification wound score 3);
* ASA-classification of IV or higher;
* Ejection fraction <30%;
* MAC score >2;
* Target lesions not amenable for endovascular treatment by operators* decision after baseline angiography (Angio-1);
* Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2024
Enrollment:	52
Type:	Anticipated

Medical products/devices used

Generic name:	OptiCross IVUS catheter
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	28-02-2024
Application type:	First submission
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	NL84441.100.23