Critical Limb Ischemia: MRA And CTA Study (Feasibility)

Published: 12-04-2012
Last updated: 28-04-2024

The main objective of this pilot study is to evaluate the burden of an additional CTA and MRA procedure in patients, and to evaluate the quality of the CTA and MRA protocols.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON37452

Source
ToetsingOnline

Brief title
CLIMACS-F

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
critical limb ischemia, severe peripheral vascular disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Critical limb ischemia, CTA, Digital subtraction angiography, MRA

Outcome measures

Primary outcome

The main study parameter is the burden for the patient of CTA and MRA expressed as the score of the visual analogue scale (VAS) and on a 5-point Likert scale.

Secondary outcome

The diagnostic accuracy of CTA and MRA to identify arterial stenoses > 50% and occlusions in patients with CLI will be compared to DSA as the reference standard.

Interobserver agreement for grading arterial stenosis and occlusions with CTA and MRA in patients with CLI will be expressed as weighted *-values.

The correlation between arterial calcifications and the diagnostic accuracy of CTA and MRA to identify arterial stenosis and occlusion in patients with CLI will be evaluated.

Study description

Background summary

Critical limb ischemia (CLI) is a severe symptom of peripheral arterial disease (PAD) and is characterized by ischemic pain at rest or non-healing ischemic ulcers or gangrene in the lower extremity. Diagnostic imaging is crucial for evaluation and management of CLI. Currently, digital subtraction angiography is the established modality for evaluating CLI. However, digital subtraction angiography is invasive and carries a risk of complications. Non-invasive imaging modalities such as computed tomography angiography (CTA) and magnetic resonance angiography (MRA) have a high diagnostic accuracy for assessment of lower extremity arterial disease in patients with claudication, but have not been thoroughly evaluated in patients with CLI. Also, there are no head-to-head comparisons of CTA and MRA in patients with CLI. Performing a direct comparison of CTA and MRA with digital subtraction angiography brings practical and ethical challenges, because of the burden for the patient. Therefore, we will first perform a feasibility study to assess the feasibility of a larger study,

which would compare the diagnostic performance of CTA and MRA with digital subtraction angiography as reference standard.

Study objective

The main objective of this pilot study is to evaluate the burden of an additional CTA and MRA procedure in patients, and to evaluate the quality of the CTA and MRA protocols.

Study design

The study is a cross-sectional feasibility study to determine the burden of CTA and MRA. It is also a preliminary study of the diagnostic accuracy of CTA and MRA that is used to guide a future larger diagnostic study. All included patients will be evaluated with CTA, MRA and digital subtraction angiography. Since the interventional radiologist may perform interventions during digital subtraction angiography, both CTA and MRA will be performed before digital subtraction angiography. All imaging procedures will be performed within seven days. There are no restrictions as to which imaging modality, CTA or MRA is performed first.

Study burden and risks

Participation to this study will not be beneficial for the patient. The patient will be exposed to 12 mSv radiation from the CTA procedure, which gives an additional risk for cancer. See appendix 8 for the advice on radiation exposure. Furthermore, for both the CTA and MRA procedure contrast will be given, respectively iodinated contrast and gadolinium. For iodinated contrast media the most common adverse reactions are nausea, feeling of pain or heat, and headache. These occur in less than 1% of the patients. Other, more severe adverse reactions are allergic reactions and contrast induced nephropathy. See appendix 9 for the summary of product characteristics of Ultravist.
The most common adverse reactions of gadolinium are headache, dizziness, taste disorders, numb and tingling feeling, vascular dilation, nausea and pain or reactions at the site of puncture. These occur in less than 1% of the patients. The risk for nephrogenic systemic fibrosis will be minimal, since patients with renal failure are excluded from this trial. See appendix 10 for the summary of product characteristics of Gadovist.
The burden of the patients according to the standard procedures of this hospital account for both the CTA and MRA procedure, since primary imaging is performed using DUS. However, several hospitals in the Netherlands, e.g. Leiden University Medical Center and Erasmus Medical Center Rotterdam, perform a CTA in patients with CLI before referring for DSA. In these hospitals, this study would imply only an additional burden of just one modality, i.e. MRA.
Until now, the vast majority of patients included in comparative diagnostic studies of CTA and MRA had complaints of IC, and not CLI. As explained in

chapter 3, patients with IC and CLI differ on many aspects, such as location and severity of disease. As a consequence, imaging recommendation for IC is not automatically valid for CLI. Adequate recommendations are therefore difficult considering which imaging modality to perform in patients with CLI. To perform an adequate comparison between CTA and MRA in patients with CLI, and to find an adequate replacement for the diagnostic DSA, we believe the only adequate way is to perform the CTA and MRA in the same patient. Before performing such a study, we first have to assess its feasibility since we realize that undergoing both CTA and MRA is hard for these patients. Therefore, we first have to perform a study to assess the patients* burden, the quality of our CTA and MRA protocols and the inclusion rate of patients.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Critical limb ischemia > 2 weeks
ankle-brachial pressure index < 0.7, or toe pressure < 50 mmHg
Referred for digital subtraction angiography
Normal renal function, defined as eGFR > 60 ml/min
Written informed consent

Exclusion criteria

Inability to give informed consent
Contraindications for MRI, i.e. metal implants or claustrophobia
Contraindications for CTA, i.e. allergic reactions to iodinated contrast agents, hyperthyroidism, goiter or pregnancy
Patient participates in another study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-04-2012
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL37723.018.11