Virtual Monoenergetic Imaging of the Lower Extremities Using Dual-Energy CT Angiography in Patients with Diabetes Mellitus: A Randomized Controlled Trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON57087

Source
ToetsingOnline

Brief title
DECTA of lower extremities in patients with DM: RCT

Condition

- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Diabetes, peripheral vascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Wetenschapscommissie HMC

Intervention

Keyword: Diabetes Mellitus, Dual energy CT, Lower extremity, peripheral arterial disease (PAD)

Outcome measures

Primary outcome

Primary endpoints are scores on image quality, image noise and vessel contrast on a 5 point scale (see chapter 3, table 1 of our research protocol) on both dual energy CTA and conventional CTA. Two experienced radiologists will score the CT-images.

Secondary outcome

- Secondary endpoints are signal to noise ratio (SNR) and contrast to noise ratio (CNR). Attenuation values (HU) and standard deviation (SD) are quantified in lower leg arteries, subcutaneous fat and iliopsoas muscle in both DECTA and conventional CTA by a radiologist. The following formula is used to determine SNR and CNR:

SNR=(HU,artery)/(SD,fat)

CNR=((HU,artery-HU,muscle))/(SD,fat)

- Total radiation dose will be automatically quantified by the CT-scan

- To evaluate the diagnostic accuracy of DECTA and conventional CTA in detecting stenosis or occlusions in the lower legs compared to DSA as gold standard; assessed by sensitivity, specificity, and area under the receiver

operating characteristic curve. This will be subgroup analysis, performed in

participants who had a DSA within 60 days of their CTA as part of standard

care.

Study description

Background summary

Type 2 diabetes mellitus (DM) is the most common metabolic disorder in the world and a major risk factor for cardiovascular disease, given its high prevalence. Peripheral arterial disease (PAD) in the lower legs represents a major complication of type 2 diabetes, often causing ischemic ulceration, gangrene and amputation.
While digital subtraction angiography (DSA) remains the gold standard for diagnosis of PAD, its invasive and time-consuming character makes it unsuitable to use in a large group of patients. Therefore, computed tomography angiography (CTA) is currently the method of choice for diagnosing PAD in the lower legs.
Dual-energy CTA (DECTA) has several advantages over conventional CTA, due to different applications such as virtual mono-energetic imaging (VMI) and bone removal software. DECTA uses raw data from high and low energy radiation (high- and low-keV) beams to create low-keV images to improve image contrast and iodine signal. In recent years, several studies have shown that VMI reconstructions provide the best image contrast with the least possible noise in low-keV reconstructions.
Often, patients suffering from PAD show reduced iodine levels in the lower legs due to significant stenosis or occlusion upstream. Additionally, evaluation of the lower leg arteries in patients with PAD is often challenged by medial arterial calcifications causing blooming artefacts. Therefore, imaging of the lower legs in this particular group of patients can benefit from DECTA.

Study objective

Several observational studies have been published evaluating DECTA for imaging of the lower legs, comparing this technique with conventional CTA.
However, to the best of our knowledge, no randomised controlled trial has been conducted comparing both conventional CTA and DECTA in patients with DM suffering from PAD.
Thus, the purpose of our randomised controlled trial is to evaluate the diagnostic accuracy and clinical utility of dual energy CTA using VMI with conventional CTA in assessing PAD of the lower extremities in patients with Rutherford stage 4 or higher. Additionally, it will explore the potential benefits of DECTA in terms of image quality, radiation dose reduction, and

visualization of small vessels.

Study design

We aim to conduct a double blind randomized controlled trail conducted at Haaglanden Medisch Centrum (HMC), The Hague (The Netherlands). Patients with diabetes mellitus who are scheduled to undergo a CTA of their lower legs for suspected arterial disease with Rutherford stage 4 or higher will be recruited at the outpatient clinic for vascular surgery or the 'Eerste Diabetische Voethulp' outpatient clinic.
Participants will be randomly assigned to one of two study groups: one group will undergo a dual-energy CTA with VMI reconstructions (DECTA group) and the other group will undergo the conventional mono-energetic CTA (CCTA group). Imaging parameters and details concerning contrast media administation can be found in chapter 3 of our researchprotocol.
Two blinded, experienced interventional radiologist will score the DECTA and conventional CTA using a five point scale to asses image quality, image noise and vessel contrast (Table 1 in our research protocol).

Study burden and risks

Participants are refered to the department of radiology for a CT scan of the abdomen and lower extrimities as part of the standard care. Participants will undergo either a dual energy CTA or a conventional CTA; both have a similar radiation dose and similar of iodine dosage. There will be no extra risk associated with participation. As the study consists of only one CTA-scan, no additional hospital visits are necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adult patients (aged 18 years and above).
- Confirmed diagnosis of diabetes mellitus and critical limb ischemia (Rutherford classification stage 4 and higher)
- Scheduled for lower extremity CTA for suspected arterial disease.
- Signed informed consent papers

Exclusion criteria

- Severe renal impairment (glomerular filtration rate <30 mL/min/1.73 m²).
- Inability to tolerate CTA procedure (e.g., severe claustrophobia).
- Contraindication to iodinated contrast media (e.g. severe allergy).
- Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	135
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-11-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL87141.058.24