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Using dynamic 4D-CT imaging to measure the blood flow in the arteries and muscles to evaluate wounds in diabetic feet

Submission date
13/03/2023

Recruitment status
No longer recruiting

Registration date
14/03/2023

Overall study status
Completed

Last Edited
15/09/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Critical limb ischemia is a serious condition in people with diabetes that can lead to death or amputation. Doctors use a procedure called intra-arterial digital subtraction angiography (IADSA) to decide the best way to restore blood flow, but this method has limitations. This study aims to use a new technique called dynamic 4D-CT imaging with a small amount of contrast dye to measure blood flow and tissue health in the foot.

Who can participate?
Patients from the diabetic foot clinic with suspected critical limb ischemia referred for clinical IADSA as part of their vascular workup.

What does the study involve?
The participants receive a low-volume (2 mL) intra-arterial 4D contrast CT examination combined with a diagnostic IADSA examination.

What are the possible benefits and risks of participating?
The 4D-CT scans might provide additional hemodyanmic information which could be used by the vascular surgeon to optimize treatment planning. The minimal usage of contrast agent (2 mL) ensures low risks related to contrast media (nausea, headache, kidney damage). The estimated effective dose (<1 mSv, ICRP-103) is lower than the natural background radiation.

Where is the study run from?
Vrije Universiteit Brussel (Belgium)

When is the study starting and how long is it expected to run for?
March 2019 to February 2023

Who is funding the study?
Fonds Wetenschappelijk Onderzoek (Flemish Research Foundation) (Belgium)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
DFPCT_V1

Study information

Scientific Title
Combined evaluation of blood flow and tissue perfusion in diabetic feet by contrast-enhanced 4D-CT imaging

Acronym
DFPCT

Study objectives
The advent of wide beam CT scanners allow to perform multiple CT acquisitions over the same structure at a high frame rate, enabling to obtain dynamic CTA data. Potential benefits of such dynamic series can be identified as morphological, hemodynamic, and functional.

This study aims at exploiting these dynamic acquisitions for improved anatomic and hemodynamic information in patients with foot ulcers by assessing the arterial blood flow and tissue perfusion low-volume contrast injections. This could lead to a new method for optimized treatment planning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2019, Medical Ethics Committee UZ Brussel (Laarbeeklaan 101, 1090 Brussels, Belgium; +32 2 477 55 85; ethiek@uzbrussel.be), ref: B.U.N. 143201939233/I/U

Study design
Single-center observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Assessment of critical limb ischemia in patients with diabetes

Interventions
Patients with diabetic foot and a high suspicion of critical limb ischemia (CLI) receive a diagnostic IADSA examination as part of their vascular workup at the diabetic foot clinic. In addition, the patients receive a low-volume (2 mL) intra-arterial 4D contrast CT examination using a combined CTA and CTP protocol consisting of multiple 160 mm axial series at different interphase delays for a total duration of 194s. Foot ulcers and stenoses are assessed by the vascular surgeon using the IADSA data to plan the treatment.

Intervention Type
Other

Primary outcome(s)
Arterial blood flow and tissue perfusion are quantified voxel-wise from 4D-CT data using 2mL of contrast agent at a single time point

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/02/2023

Eligibility

Key inclusion criteria
1. Diabetic foot
2. Suspicion of critical limb ischemia
3. Referred for IADSA

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Known allergic reactions to iodinated contrast agents
2. Hyperthyroidism
3. Dialysis

Date of first enrolment
01/01/2021

Date of final enrolment
01/08/2021

Locations

Countries of recruitment
Belgium

Study participating centre
UZ Brussel
Laarbeeklaan 101
Brussels
Belgium
1090

Sponsor information

Organisation
Vrije Universiteit Brussel

ROR
https://ror.org/006e5kg04

Funder(s)

Funder type

Government

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, Research Foundation – Flanders, Fonds voor Wetenschappelijk Onderzoek - Vlaanderen, The FWO, Het FWO, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/07/2023	26/07/2023	Yes	No