

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

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|--------------------------|-----------------------------|--|
| <b>Submission date</b>   | <b>Recruitment status</b>   | <input type="checkbox"/> Prospectively registered    |
| 13/03/2023               | No longer recruiting        | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b> | <b>Overall study status</b> | <input type="checkbox"/> Statistical analysis plan   |
| 14/03/2023               | Completed                   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b>       | <b>Condition category</b>   | <input type="checkbox"/> Individual participant data |
| 15/09/2023               | Circulatory System          |  |

## 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 hemodynamic 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?  
Pieter Thomas Boonen (pieter.thomas.boonen@vub.be)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

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, 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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |                               | 26/07/2023   | 26/07/2023 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |