Use of [15O] H2O PET to determine lower extremity muscle perfusion in patients with peripheral artery disease

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON53834

Source
ToetsingOnline

Brief title
PEPPER trial

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral artery disease; artierial insufficiency; atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Jaap Schouten foundation

Intervention

Keyword: 15O H2O PET (water PET), Perfusion, TcPO2

Outcome measures

Primary outcome

The main endpoint of this study is to correlate regional muscle tissue perfusion measured with [15O] H2O PET to local skin tissue perfusion measured with TcPO2. We will have measurements of both legs of 15 patients, who will undergo a [15O] H2O PET scan and local skin perfusion measurements at 4 locations twice (before and after the intervention).

Secondary outcome

A secundary parameter is is to correlate pre-intervention tissue perfusion (measured with [15O] H2O PET and TcPO2) with post-intervention tissue perfusion. We will also correlate these parameters with arterial blood pressure (ABI and TBP).

Antoher secudnarry parameter is the inter- and intra-rater variability between two researchers who perform measurements on the [15O] H2O PET-scans.

Study description

Background summary

Peripheral arterial disease (PAD) of the lower extremity is a progressive and common disease caused by obstructions of the lower extremity arteries. Symptoms of PAD include pain during exercise, which can progress into chronic limb-threatening ischemia (CLTI) with pain at rest, and development of non-healing ulcers. These clinical complaints are the result of impaired tissue perfusion. To determine the severity and extent of ischemic tissue, tissue

perfusion measurements are deemed necessary. Most diagnostic techniques to establish the diagnosis of PAD can only detect stenotic lesions of the major arteries, and do not measure tissue perfusion. There are some non-invasive techniques that measure skin perfusion, but are not widely used. Transcutaneous partial pressure of oxygen (TcPO2) is one of the most often used tissue perfusion techniques and is correlated with Fontaine classification, but it has low quality of evidence and several limitations, including long measurement time (15 minutes) and high inter-rater variability.
The technique measures the perfusion of the skin at a small (1 mm2) location where the sensor is positioned. Perfusion of the skin is known to vary locally, which is why TcPO2 measurements may not always reflect the global perfusion of a limb. Therefore, there is need for a study that relates the local tissue perfusion by TcPO2 with more global perfusion of the affected limbs in PAD patients. [15O] H2O positron emission tomography (PET) is a gold standard for tissue perfusion and it is shown that the [15O] H2O PET is able to measure muscle perfusion. Currently, it is primarily used to measure myocardial perfusion in patients with coronary artery disease (CAD).

Study objective

The primary aim of this study is to correlate regional muscle perfusion measured with [15O] H2O PET in patients with advanced PAD to local skin perfusion measured with TcPO2.
Secondary objectives are to compare pre-revascularization perfusion rates with post-revascularization perfusion rates and to correlate regional muscle perfusion and local skin perfusion with arterial pressure measurements (ankle brachial index; ABI and toe systolic blood pressure; TBP) to determine a possible correlation in measuring lower limb perfusion pre- and post-revascularization.
Another secondary objective is determining the inter- and intra-observer variability in measuring local muscle perfusion with [15O] H2O PET.

Study design

This is a single centre pilot observational study with a study population of 15 patients with PAD Rutherford 4-6 in one leg and Rutherford 0-3 in the contralateral leg, who are scheduled for endovascular revascularization. For this research, patients will undergo a [15O] H2O PET scan and local skin perfusion measurements pre-intervention and 6 weeks post-intervention. Skin perfusion will be measured with TcPO2 at 4 locations of the lower legs and feet.
Standard of care pre-intervention consist of arterial pressure measurements, treadmill test if possible, duplex ultrasound and a CTa. The patients will be staged following the Rutherford classification. Part of the standard of care 6 weeks post-intervention are arterial pressure measurements, treadmill test if possible, TBP, and duplex ultrasound. Patients will be staged again at 6 weeks.

This is an observational study and the patients will receive treatment according to standard of care. The treatment choices will not be affected by the diagnostic results of the study.

Study burden and risks

There is limited risk associated with participation in this study. The [15O] H2O PET/CT gives a combined dose of 1,04mSV, which is within category IIb according to the Netherlands Commission on Radiation Dosimetry. It is less radiation then the annual background radiation per person. Therefore, there is limited risk in participation in this study. TcPO2 will be measured with the PF 6040 TcPO2 unit which is a CE-approved device and will be used in this study according to intended use. Other measurements (systemic blood pressure, local skin temperature, oxygen saturation, ABI and TBP) are routine clinical measurements, with no additional risks.

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

18 years or older; written informed consent and; chronic limb threatening ischemia (Rurtherford 4-6) at the leg that will be revascularized

Exclusion criteria

Insufficient knowledge of the Dutch language, illiteracy, language barrier or not compos mentis; lower leg fractures within the past 12 months; (partial) amputation of one of the feet and/or legs; Rutherford 4-6 at the contralateral leg; pregnant or breast feeding; severe peripheral oedema; taller than 1,90 m (because of the limited field of view of the PET scanner; the PET camera only measures 1.06m and we want to picture the entire legs); not able to lay supine for 6 minutes; acute ischemia and; severe claustrophobia.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-08-2023
Enrollment:	15
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	21-06-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-08-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL82629.042.22