

# Validation and clinical applicability PeriFlux System 5000

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Objectives of the study are to evaluate the clinical applicability of the PeriFlux System 5000 and to investigate the reproducibility of its measurements on inter- (and intra-observer) variability.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Vascular therapeutic procedures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30488

### Source

ToetsingOnline

### Brief title

Validation and clinical applicability PeriFlux System 5000

### Condition

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

### Synonym

arterial occlusive disease, atherosclerosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Het meetsysteem is kosteloos ter beschikking gesteld. Er zijn geen extra kosten verbonden aan het onderzoek., PeriMed AB, Stockholm, Zweden

## Intervention

**Keyword:** Atherosclerosis, Laser Doppler perfusion measurement, Microcirculation, Transcutaneous oxygen pressure

## Outcome measures

### Primary outcome

Primary endpoints of this study are differences in microcirculatory parameters between the Doppler and TcPO<sub>2</sub> measurements. In addition, the time needed to perform the measurements will be used as an indicator for the burden for the subject. Total time needed for measurements and analysis will be used as an indicator for clinical applicability.

### Secondary outcome

not applicable

## Study description

### Background summary

In the JUVENTAS Trial, patients with critical limb ischemia (CLI), who have no surgical or radiological revascularisation options, are treated with stem cell therapy. In order to evaluate the effects of stem cell therapy in these patients, MRA, MR-perfusion, walking test and ABI measurement are performed. To further evaluate the effects of stem cell therapy on a microcirculatory level, a microcirculatory measurement system could be used. However, before such system can be used in the Trial, its clinical applicability should be tested. Combined Laser Doppler and transcutaneous oxygen pressure measurements can be used to assess the effects of stem cell therapy on a microcirculatory level. Moreover, by using provocations like local heating or breathing 100% oxygen, the microcirculatory reserve capacity can be determined. The PeriFlux System 5000 (PeriMed) allows for simultaneous and standardised way of measuring microcirculatory parameters. Based on many publications of the past 20 years, it is expected that combined laser Doppler and transcutaneous oxygen pressure measurements, supplemented with above mentioned provocation tests, can provide a reliable representation of the microcirculatory status and reserve capacity in patients participating in the JUVENTAS Trial. However,

before the system can be used in the Trial, its clinical applicability should be tested to minimize discomfort.

### **Study objective**

Objectives of the study are to evaluate the clinical applicability of the PeriFlux System 5000 and to investigate the reproducibility of its measurements on inter- (and intra-observer) variability.

### **Study design**

In 10 patients who will receive a trombendarterectomy (TEA) or remote endarterectomy of the iliaco-femoral vessels 2 measurements by 2 independent investigators will be performed before and after surgery. By comparing the measurements of the 2 investigators, inter-observer variability can be determined. By comparing the pre- and post-surgical measurements, it can be investigated if the intended microcirculatory perfusion improvement can be measured with laser Doppler and TcpO<sub>2</sub>.

### **Study burden and risks**

The burden for the subjects is considered minimal. The burden will consist of 2 measurements before surgery (measuring time 100 minutes) and 2 measurements after surgery (also 100 minutes). The measurements are performed during regular admission to the hospital and thus do not take additional time. The measurements will be performed in a non-invasive way.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

PAOD Fontaine II of the iliacofemoral vessels that will be treated with TEA

### Exclusion criteria

Extensive PAOD Fontaine II of other (more distal) vessels

Bypass surgery

## Study design

### Design

**Study type:** Observational non 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: 12-06-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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	NL15971.041.07