Validation and clinical applicability PeriFlux System 5000

Published: 12-06-2007
Last updated: 08-05-2024

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

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vascular therapeutic procedures
Study type	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 kostenloos 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

Primairy endpoints of this study are differences in microcirculatory parameters between the Doppler and TcPO2 measurements. In addition, the time needed to perform the measurements will be used as a 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 transcuteanous 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 transcuteanous 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 reproducability 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 TcpO2.

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
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland

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