The vascular occlusion test using hyperspectral imaging: a validation study

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The aim of the study is to investigate whether hyperspectral imaging can be used as a noninvasive method for the assessment of changes in StO2 in the forearm of human volunteers during a vascular occlusion test.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43177

Source ToetsingOnline

Brief title VASOIMAGE

Condition

• Other condition

Synonym

Microvascular response; hyperemic response

Health condition

Gezonde vrijwilligers

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Forearm occlusion, Hyperspectral imaging, Microcirculation, Near-infrared spectroscopy, Vascular Occlusion Test

Outcome measures

Primary outcome

What is the level of agreement between the StO2 measured by hyperspectral

imaging and the StO2 measured by near infrared spectroscopy as gold standard

for microcirculatory measurements during a vascular occlusion test?

Secondary outcome

What are the patterns in SpO2 as measured by pulse oximetry during a vascular

occlusion test?

What are the changes in skin temperature as measured by a thermographic camera

during a vascular occlusion test?

Study description

Background summary

The microcirculation plays a crucial role in the process of tissue oxygenation, perfusion and nutritional exchange. At a microcirculation level, oxygen and carbon dioxide are exchanged, and tissue waste products eliminated. Anesthesia and surgery have a large impact on system hemodynamics, and this is subsequently associated with a wide range of changes in microcirculatory perfusion and oxygenation. Despite normalization of macrohemodynamic parameters, we previously showed that significant dysfunction of microcirculatory perfusion may persist, e.g. during cardiac surgery, even throughout the postoperative period. Moreover, our group showed that macrohemodynamic changes are not representative for microcirculatory function. Measurements of microcirculatory behavior in the clinical setting present a particular challenge, because vessel structure is inhomogeneous and perfusion is highly variable during surgery. Unfortunately, most available tools, such as Sidestream Darkfield Imaging or contrast-enhanced ultrasound may never leave the experimental setting in the context of perioperative care. The ideal tool for measuring the microcirculation would be an easy to use, non-invasive, non-contact device that provides real-time information about regional tissue oxygenation and perfusion of different organs. One emerging imaging technique may be useful in microcirculatory imaging: hyperspectral imaging (HSI). This type of imaging is based on a non-contact visualization of alterations in the tissue wavelength profile.

Study objective

The aim of the study is to investigate whether hyperspectral imaging can be used as a noninvasive method for the assessment of changes in StO2 in the forearm of human volunteers during a vascular occlusion test.

Study design

Open label, non-randomized, observational study

Intervention

Vascular occlusion test

Study burden and risks

There are no risks associated with this study. The camera's used for this study use mostly near infrared light to measure the different light spectra of oxyhemoglobin an deoxyhemoglobin. There is minimal extra burden for the volunteer consists of a forearm occlusion and a possible pain sensation. This pain sensation almost directly disappears after deflation of the blood pressure cuff.

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

In order to be eligible to participate in this study, a volunteer must meet all of the following criteria:

* Age: 18 - 65 years old

- * Male and female from all ethnicities
- * Informed consent

Exclusion criteria

A potential participant in this study who meets any of the following criteria will be excluded from participation in this study:

- * Renaud*s disease
- * Peripheral vascular dysfunction
- * Infectious diseases.
- * Burns of the skin of the arms
- * Diabetes Mellitus type I or II
- * Volunteers with a left-right difference in systolic blood pressure >10mmHg at the wrists

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2016
Enrollment:	50
Туре:	Actual

Medical products/devices used

Generic name:	hyperspectral imaging;thermal imaging;near-infrared spectroscopy
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO	
Date:	30-09-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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

ССМО

ID NL56684.029.16