Validation of Laser Speckle Imaging

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22543

Source
Nationaal Trial Register

Brief title
VALSI

Health condition

none

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

It is expected that the results from this project will provide new insights into the use and interpretation of different kind of LSCI devices in clinical practice and researches.

• The primary objectives
o To test the comparebility of two different model LSCI devices in terms of baseline, supra- and infra-physiologic blood flows.
o To validate the non-validated LSCI device (Perimed (Järfälla, Sweden)) with a gold standart

method (Cytocam-IDF).

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Secondary outcome

The secondary objectives
o To assess the response of the LSCI devices during PORH
o To understand differences between the different kind of LSCI devices in terms of physiologic responses
o To assess and define normal blood flow values of the normal population.

Study description

Background summary

Laser speckle contrast imaging (LSCI) is a technique based on speckle contrast analysis that provides an index of blood flow and have been generated widespread interest for clinical use in microvascular monitoring. No need for skin contact, continuous and real time assessment of the microcirculation led the LSCI to be broadly used in clinical practice. Currently, there are two different LSCI devices of two companies, Moor Instruments (Devon, UK) LSCI and Pericam PSI System (Perimed AB, Järfälla, Sweden) LSCI. Despite the devices work with the same principle and the increased number of the researches with both, comparability of the devices has not been searched yet. In addition, a difficulty remains in the interpretation of the findings due to using arbitrary unit for defining blood flow.
In clinical research and practice, assessment of the microcirculatory function is of utmost importance especially during medical interventions and the monitoring of disease progression. Microvascular perfusion can be assessed directly using laser doppler flowmetry, laser speckle contrast imaging, nail fold microscopy, orthogonal polarization spectral imaging (OPS), side stream dark field imaging (SDF) and incident dark field technique (Cytocam-IDF). Video microscopes are known as the gold standard techniques for microcirculatory assessment due to direct visualization of the actual state of the microcirculation. Moor LSCI (Devon, UK) device has already been validated with the first generation video microscope orthogonal polarization spectral imaging (OPS), however Perimed (Järfälla, Sweden) LSCI device is not validated yet.
In this study we aim to validate LSCI device which has not been validated yet. In addition, we aim to test the comparability of two different model LSCI devices.

Study objective

It is hypothesised that both laser devices will be highly comparable

Study design

T is 0, T is 1,T is 2,T is 3 minutes

Contacts

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Eligibility criteria

Inclusion criteria

Healthy human volunteers older than 18 years old who conform to following criteria
• Should not have any disease now including flu
• Should not have any disease known before
• Should not be under any medication
• Should not drink coffee or eat meal in two hours before the procedure

Exclusion criteria

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

• Volunteer who does not meet any of the criteria above
• <18 years old
• Pregnants
• Maastad Ziekenhuis employers/colleagues
• Refusal to participate in the study or demand to end study for any reason

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-12-2019
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8984
Other	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam en omstreken : Protocol 2018-41 VALSI Studie, Scientific buro Maasstad Hospital

Study results