Validation of Laser Speckle Imaging

Gepubliceerd: 11-10-2020 Laatst bijgewerkt: 18-08-2022

It is hypothesised that both laser devices will be highly comparable

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22543

Bron
NTR

Verkorte titel
VALSI

Aandoening

none

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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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Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

It is hypothesised that both laser devices will be highly comparable

Onderzoeksopzet

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

Contactpersonen

Publiek

Maasstad Ziekenhuis
annemieke dijkstra

0615866102

Wetenschappelijk

Maasstad Ziekenhuis
annemieke dijkstra

0615866102

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-12-2019
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten