Feasibility study of a hyperspectral imaging system in detection of human skin perfusion and oxygenation

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28750

Source
Nationaal Trial Register

Brief title
HCS-Perfusion trial

Health condition

tissue oxygenation, tissue perfusion

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: European Union Horizon 2020 Program

Intervention

Outcome measures

Primary outcome

feasibility, applicability, and reproducibility of a novel hyperspectral camera system in perfusion and oxygenation detection in healthy volunteers.

Secondary outcome

Hyperspectral measures of:

1. basal blood flow / oximetry

2. blood flow /oximetry upon occlusion-reperfusion brachial artery

3. Blood flow / oximetry after applying capsaicin-based cream

4. Blood flow/ oximetry after applying brimonidine

Study description

Background summary

Restoring normal functioning and tissue healing after surgical intervention is, among others, critically dependent on tissue oxygenation and perfusion. Currently, several optical techniques, which do not require administration of contrast agents, have been used to evaluate tissue perfusion and oxygenation. An emerging technique is hyperspectral imaging, which is capable to detect the scattering and absorption of light delivered to the tissue, caused by inhomogeneity of biological structures, such as haemoglobin, fat or water. In this study the effect of occlusion-reperfusion of the brachial artery on cutaneous blood oxygenation is explored in eight human volunteers as assessed by a snapshot hyperspectral camera system. Furthermore, measurements of local changes in skin oxygenation and blood flow after applying a local vasodilator (capsaicin-based cream) and a local vasoconstrictor (brimonidine gel) are compared to measurements of an untreated area of the skin. Simultaneously with the hyperspectral measurements, real-time blood perfusion mapping is performed using Laser Speckle Contrast Imaging, which is able to detect individual moving particles such as blood cells.

Study objective

We hypothese that this hyperspectral camera system is able to detect physiological changes in the oxygenation and perfusion of the skin in healthy human volunteers.

Study design

Experiments will be repeated 3-28 days later in order to evaluate the reproducability.

Intervention

hyperspectral images will be made after induction of occlusion, local vasoconstriction and

vasodilation of the forearm of the volunteers.

Contacts

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Eligibility criteria

Inclusion criteria

- Healthy volunteers, 18 to 45 years of age, inclusive. Healthy status is defined by absence of evidence of any active or chronic disease following a detailed medical and surgical history.

- Body mass index (BMI) between 18 and 30 kg/m2, inclusive, and with a minimum weight of 50 kg.

- Able to participate and willing to give written informed consent and to comply with the study restrictions.

Exclusion criteria

- History or symptoms of any significant disease including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder.

- Systolic blood pressure (SBP) greater than 140 or less than 90 mm Hg, and diastolic blood pressure (DBP) greater than 90 or less than 50 mm Hg.

- Use of any medications (prescription or over-the-counter [OTC]), vitamin, mineral, herbal, and dietary supplements within 21 days of study drug administration, or less than 5 half-lives

(whichever is longer). Exceptions are paracetamol (up to 4 g/day). Other exceptions will only be made if the rationale is discussed and clearly documented between the Investigator and the sponsor.

- Concomitant disease or condition that could interfere with, or for which the treatment of might interfere with, the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the subject in this study.

- Smokers as defined by any of the following criteria:

o Reported smoking of cigarettes within 12 months prior to screening; occasionally a cigarette is allowed, but not within 24 hours of the measurements.

- Any confirmed significant allergic reactions (urticaria or anaphylaxis) against any drug, or multiple drug allergies (non-active hay fever is acceptable).

- Unwillingness or inability to comply with the study protocol for any other reason.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2018
Enrollment:	8
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	05-12-2018
Application type:	First submission

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	NL6381
NTR-old	NTR7654
Other	Commissie Medische Ethiek van het LUMC : P17.288

Study results