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

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Primary Objective: To investigate the feasibility, applicability, and reproducibility of a novel hyperspectral camera system in perfusion and oxygenation detection in healthy volunteers.Secondary Objectives: - To explore the effect of occlusion-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46360

Source
ToetsingOnline

Brief title
HCS-perfusion

Condition

- Other condition

Synonym
N.A.

Health condition

Perfusie gerelateerde stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Horizon 2020 grant: ASTONISH (project ID: 692470)

Intervention

Keyword: hyperspectral camera, tissue oxygenation imaging, tissue perfusion imaging

Outcome measures

Primary outcome

1) Feasibility and applicability is achieved as the researchers were able to

produce hyperspectral images, which were available to analysis without too much

noise caused by an unstandardized measurements.

2) Reproducibility is measured by repeating the measurements on two different

days in the same study population. Therefore, the following parameters will be

evaluated by LSCI:

- Basal blood flow

- Blood blow upon occlusion-reperfusion brachial artery

- Blood flow after applying capsaicin-based cream and brimonidine

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

The endpoint of the study is if a selection of spectral bands, specific for

tissue perfusion and oxygenation, which will be selected after data processing

of above mentioned measurements, could be achieved.

Study description

Background summary

Feasibility and reproducibility of a hyperspectral camera system in human skin perfusion and oxygenation detection will be evaluated, resulting in selection of spectral bands, which could be used in clinical practice.

Study objective

Primary Objective:

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

Secondary Objectives:

- To explore the effect of occlusion-reperfusion of the brachial artery on cutaneous blood flow as assessed by a hyperspectral camera system.
- To explore the effect of applying topical vasoconstrictors / vasodilators on the cutaneous blood flow as assessed by a hyperspectral camera system.
- Selection of relevant spectral bands for oxygenation and perfusion detection.

Study design

Open observational multicenter study.

Intervention

To induce local vasoconstriction and vasodilatation, brimonidine cream and capsaicin cream will be applied on the forearm of the volunteers.

Study burden and risks

This study is a non-therapeutic trial, which evaluates the feasibility of the hyperspectral camera system in evaluation of the tissue perfusion and

oxygenation in different circumstances. The main aim of this study is to select relevant spectral bands for oxygenation and perfusion detection, which can be used for further camera development and consequently in clinical practice. There is no benefit for the recruited healthy human volunteers upon participation to this study. However, the expected risks are minimal. The hyperspectral imaging system uses halogen light, which is also widely used as a commercial light source. The risk of drug side effects will be minimized by accurate selection of volunteers. Moreover, the experiments will take place in a controlled hospital setting.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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.

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: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).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

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

Medical products/devices used

Generic name:	Hyperspectral camera (prototype)
Registration:	No

Ethics review

Approved WMO Date:	17-05-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL63242.058.17

Study results

Date completed:	01-10-2019
Actual enrolment:	8