Validation of noninvasive hemoglobin analysis by spectroscopic optical coherence tomography

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Observational invasive

Summary

ID

NL-OMON51391

Source
ToetsingOnline

Brief title
Optical blood analysis

Condition

- Anaemias nonhaemolytic and marrow depression

Synonym
anemia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Netherlands Organ-on-Chip Initiative (NOCI);an NWO (Netherlands Organisation for Scientific Research) Gravitation project funded

by the Ministry of Education;Culture and Science of the government of the Netherlands (024.003.001)

Intervention

Keyword: blood, hemoglobin, noninvasive, optics

Outcome measures

Primary outcome

The main study parameter is the agreement between tHb determined by sOCT and

the tHb determined by invasive blood sampling.

Secondary outcome

n.a.

Study description

Background summary

Quantification of total haemoglobin concentrations (tHb) is a key step in the diagnosis of haematologic disorders. The current gold standard for this procedure is invasive venous blood sampling, followed by laboratory analysis of the tHb. This procedure is disadvantageous for vulnerable patient groups (e.g. premature infants) and hampers the possibility for continuous monitoring.
We hypothesize that spectroscopic optical coherence tomography (sOCT) can quantify the tHb in a non-invasive manner. sOCT obtains the tHb from 3D images of the microcirculation in the skin or sublingual/sublabial tissue, by quantifying the optical absorption of hemoglobin with low power light. In a recent pilot non-WMO study on healthy volunteers, we demonstrated that the tHb determined by sOCT falls within the healthy biological range. The next step - described in this protocol - is a validation study, in which we compare the tHb determined by sOCT to the gold standard, invasive blood sampling.

Study objective

The objective of this study is to validate the tHb determined by sOCT by comparing it to the tHb from invasive blood sampling. From this comparison, we aim to optimize our data analysis procedure for in vivo sOCT measurements. We also aim to determine the precision of sOCT for noninvasive tHb determination.

Study design

Observational, proof-of-concept study

Study burden and risks

The burden per participant will be restricted to a one-time sOCT measurement session and a one-time standard invasive venous blood withdrawal procedure.
- The non-invasive sOCT measurements use low-power light, are pain free, safe and do not interfere with the physiology of the microcirculation. During the measurements, a steering laser beam will scan a region of interest at the skin. Completing a scan takes ~2 minutes, in which the subject must remain in a static, relaxed position. Multiple scans at different locations will be acquired, demanding a total time of ~30 minutes. In this process, no mechanical components will touch the participant and also electrical risks are absent. All surfaces that are in contact with the participant during the sOCT measurement will be sterilized before and after each measurement session.
- The standard venous blood withdrawal procedure will be performed at the antecubital area (i.e. the bend of the elbow), requires 5 mL blood and takes around 5 minutes. Blood sampling will be performed by a skilled and qualified analyst of the TechMed Centre donor service of the University of Twente, while adhering to the hygiene standards for blood draws (hand hygiene, skin sterilization, sterile needles and equipment). This minimizes the risks of pain, bleeding, fainting, bruising, infection and/or hematoma at the injection site.
Participation in this study does not provide any direct benefit to the participants. If the outcome of this study demonstrates that sOCT can quantify the tHb with sufficient precision, this may eventually result in a benefit for future patients who require a tHb determination. For those patients, a non-invasive sOCT determination can potentially replace the current invasive gold standard.

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

adult, age 18 years and up

Exclusion criteria

- hematologic disorders
- abnormal skin conditions (e.g. psoriasis) at the desired measurement location

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2023
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	spectroscopic optical coherence tomography system
Registration:	No

Ethics review

Approved WMO Date:	09-11-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL82633.091.22