Measuring oxygen saturation in the retina with a modified fundus camera

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Primary Objective:The primary objective is to investigate whether the retinal SpO2 - measured with invisible, NIR light - changes as a function of simulated height in the same way as the SpO2 measured with the standard finger clip.Secondary…

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53180

Source
ToetsingOnline

Brief title
Measuring hypoxia in the retina

Condition

- Other condition

Synonym
hypoxia, oxygen deficiency

Health condition

hypoxie

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: ministerie van Defensie

Intervention

Keyword: hypoxia, oximetry, retina

Outcome measures

Primary outcome

The primary outcome measure is the SpO2 in the retina at different simulated heights. The data is collected with the adapted fundus camera. The criterion validity of the data is assessed by comparing the data with data measured with a reference method (finger NIRS, WristOx 3150 with 8000SM-WO2 soft sensor, Nonin Medical Inc, Plymouth, USA).

Secondary outcome

A secondary outcome measure is heart rate (beats per minute) measured in the retina. The twilight lighting conditions may make it possible to distill the heart rate from data measured with the modified fundus camera. The validity of the data is again assessed by comparing it with data measured with the above reference method (finger NIRS, WristOx 3150 with 8000SM-WO2 soft sensor, Nonin Medical Inc, Plymouth, USA).

Study description

Background summary

Oxygen deprivation to the brain (hypoxia) is an identified problem for military pilots and can be caused by G-forces and flying at altitude. Hypoxia can lead to impaired decision making and even unconsciousness. Unfortunately, there is

still no suitable technology available to measure cerebral oxygen supply in pilots. Over the years, TNO and the Center for Man and Aviation (CML) have tested several non-invasive sensors, such as the Finapres® (measuring blood pressure with a finger clip sensor) and NIRS (Near InfraRed Spectroscopy through the skin). The problem with these sensors, however, is that they do not measure close enough to the brain (finger clip sensor), or provide relative values **(NIRS), which are not predictive of the oxygen supply in a pilot's brain.
In a previous feasibility study (TNO 2021 R12701, Feasibility Study on Retinal Pulse Oximetry using Near InfraRed (NIR) Light) we investigated a new, more direct way of measuring cerebral oxygen saturation and arterial blood pressure, using a visually accessible offshoot of the brain: the retina. The brain and retina are supplied with oxygenated blood by the same artery and are geometrically close to each other, making it plausible that the oxygen supply and blood pulsation/pressure in the brain are reflected in the retina. Although measuring the oxygen content of the retinal vessels (retinal oximetry) had been done before, our approach differs due to the wavelengths used. Unlike clinical monitoring of retinal oxygenation, our method needs to be invisible to the military user, so we use near-infrared (NIR) light that is invisible to the human eye. In this wavelength range, blood absorbs little, which makes it challenging to extract reliable information from the retina. That's why it has never been done. To vary the atmospheric pressure, the feasibility study used the hypobaric chamber of the CML. Altitudes of 0, 6000, 9000 and 12000 ft have been simulated, leading to an oxygen saturation (SpO2) varying between approximately 80-100%. A comparison with a finger clip sensor (Nonin WristOx 3150 with 8000SM-WO2 soft sensor) suggests that it is quite possible to estimate SpO2 based on NIR images of the retina. In contrast, the estimated heart rate (HR) was unreliable, possibly due to interfering ambient light. In the current study, we want to expand the dataset with measurements on a larger group of test subjects, improve the lighting conditions and filter wavelengths of the fundus camera.

The importance of this research is that this technology, in collaboration with industry, could eventually be integrated into the helmet mounted display (HMD) of pilots. Such technology can detect oxygen deficiency in the brains of pilots at an early stage and thus prevent accidents.

Study objective

Primary Objective:
The primary objective is to investigate whether the retinal SpO2 - measured with invisible, NIR light - changes as a function of simulated height in the same way as the SpO2 measured with the standard finger clip.

Secondary Objective:
The second goal is to investigate whether improved lighting conditions compared to the earlier feasibility study make it possible to measure HR in the retina

with NIR light (in addition to SpO2).

Study design

It concerns a validation study of a measurement method. The criterion validity of a new measurement method for measuring oxygen saturation and heart rate is mapped by determining correlations with the gold standard method. Using repeated measurements, participants are exposed to four simulated heights.

Study burden and risks

The burden on participants is low, the procedures are standard and the risks, partly due to the medical examination prior to participation, are low. Participants are instructed to report if they are not feeling well and oxygen is administered. In addition, participants are monitored during the experiment by a physician familiar with hypoxia-related phenomena. The retinal images are non-invasive and are made with a modified CE-certified fundus camera, using a limited amount of NIR light.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• You are healthy (as defined in the criteria below). • You are between 18 and 50 years old. • You don't smoke. • You are not pregnant. • You have a BMI between 18 and 25 kg/m2. BMI formula: weight in kilograms / (height in meters * height in meters). • You do not drink alcohol on the evening before the start of the test day. • You have not used any drugs in the past 3 months. • You are prepared to undergo a medical examination, consisting of a short physical examination, completing a few questionnaires and a short ECG. • You have no cardiovascular disorders. • You are not familiar with psychiatric and/or neurological disorders. • You do not have chronic anemia. • You are not claustrophobic and able to spend an hour in a confined space. • You have not donated blood in the past 72 hours • You are not overly sensitive to airsickness (a form of motion sickness, where you become ill from a flight). • You have not been at altitude (>2000m) for more than a week in the past 3 months. • You accept that the collected data will be stored and processed in encrypted form, archived for at least 10 years and possibly published.

Exclusion criteria

none, other than not fulfilling the inclusion criteria

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	09-10-2023
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	fundus camera
Registration:	No

Ethics review

Approved WMO Date:	27-07-2023
Application type:	First submission
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	NL84262.058.23