High resolution imaging of the oxygen saturation and hemoglobin concentration in retinal blood vessels

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Primary Objective: Non- invasive determination of the oxygenation values and the haemoglobin concentration of retinal arteries and veins by means of retinal imaging.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular structural change, deposit and degeneration NEC
Study type	Observational invasive

Summary

ID

NL-OMON46160

Source
ToetsingOnline

Brief title
Retoxy

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym
Diabetes, glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Heidelberg Engineering,Heidelberg

Engineering GmbH

Intervention

Keyword: heamoglobin, imaging, ophthalmology, oxygen saturation

Outcome measures

Primary outcome

This study will evaluate the application of a newly developed MCSLO for Non-invasive determination of the oxygenation values and the haemoglobin concentration of retinal arteries and veins

Secondary outcome

NA

Study description

Background summary

The proper retinal functioning depends on the availability of a sufficient amount of oxygen. Therefore, measuring the amount of oxygen present in the retinal vessels is important in order to detect and monitor diseases such as glaucoma and diabetic retinopathy (DR). The main chromophore of blood is haemoglobin. The absorption of haemoglobin varies based on the oxygenation for most wavelengths except for few wavelengths which are called isosbestic wavelengths. Haemoglobin oxygen saturation is the percentage of oxyhemoglobin (HbO2) out of total haemoglobin content in blood. Several retinal diseases result in reduced oxygen circulation in the retina causing hypoxia, which is one of the key drivers of angiogenesis. As such, measuring the retinal blood oxygen saturation will enable monitoring of the development of hypoxia and thus will allow preventing the loss of retinal tissue due to vasoproliferation through timely therapeutic interventions. The light intensity after interaction of light with blood is estimated by the brightness value of the vessel. This (reflected) brightness value is affected by light absorbance by blood in the vessel. The reference light intensity is estimated by the brightness value of next to the vessel of interest (in the tissue). This brightness value is not affected by light absorbance by the blood vessel. By choosing a brightness value close to the vessel for the reference, the light intensities are affected by similar factors except for the light absorbance by the vessel. Measuring the

absorption at least two wavelengths yield the saturation of the blood.

Non-invasive monitoring of haemoglobin concentration would be quite helpful for various clinical purposes. Continuous monitoring is essential for patients with blood-related disorders, in emergency situations, in field conditions, or with treatments that interfere with Hb-forming in the body. Continuous monitoring might also be beneficial to establish a connection between anaemia and other age-related or systemic diseases. For example, a recent cross-sectional study suggested that high haemoglobin levels indicate decreased risk of diabetic retinopathy. Measuring the Hb concentration together with retinal oximetry and blood flow would indicate total metabolic demand of the retina.

The study is an observational pilot study, to determine the feasibility of non-invasive determination of the oxygenation values and the haemoglobin concentration of retinal arteries and veins using an MCSLO. Thus, we select a population comprising of healthy volunteers between 18 to 68 years of age.

Study objective

Primary Objective: Non- invasive determination of the oxygenation values and the haemoglobin concentration of retinal arteries and veins by means of retinal imaging.

Study design

The study is an observational pilot study, proof of concept to determine the feasibility of non- invasive determination of the oxygenation values and the haemoglobin concentration of retinal arteries and veins using a MCSLO.
Day 1: Study subjects undergo a baseline ophthalmological investigation which will take 30 minutes.
Day 1 and an arbitrary days after day one in case of multiple visits:
Subjects receive mydriatic eye drops to dilate the pupil. Subjects are asked to look in an optical system where the retina is illuminated with different colors of light. Time: about 15 minutes per visit. If the subject consents, a point of care analyzer requiring a finger prick to draw 8 µliter will be used to asses hemoglobin concentration.

Repeat visits might be necessary due to continuing improvements to the experimental device and to validate repeatability of the measurements

Study burden and risks

Risks are minimal, the measurement method is non-invasive, there will be no contact with the eye. The illumination of the retina is in accordance with European standard IEC 60825-1. To improve the quality of the MCSLO images, pupil dilatation is necessary with a topical mydriatic (Tropicamide). Pupil

dilatation may cause a modest amount of transient photophobia and blurred vision in some participants, lasting several hours. This may interfere with car driving, so patients are advised not to drive themselves. Adverse ocular or systemic side effects of Tropicamide are very rare. Baseline ophthalmological investigations include a slit lamp examination and eye pressure measurement to exclude risk factors such as increased pressure in the eye or a narrow anterior chamber angle that could put the participant at risk for angle-closure glaucoma. Overall, the risks involved in this study are very low and are acceptable for the subjects participating in the study.

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

Healthy volunteer, Eye correction between -5 and 5 Dioptre

Exclusion criteria

Risk of small angle closure

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):	25-01-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	High resolution imaging of the oxygen saturation and hemoglobin concentration in retinal blood ves
Registration:	No

Ethics review

Approved WMO

Date:	15-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL67942.029.18