The CORIMAP study - A comparison study between a prototype retinal handheld oximeter (CORIMAP camera) and the Oxymap T1

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON43401

Source
ToetsingOnline

Brief title
CORIMAP study

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retina saturation, retinal oximetry

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: ODAS

Intervention

Keyword: Oximeter, Oxygen, Retina, Retinal oximetry

Outcome measures

Primary outcome

The ODR will be determined in three different situations (Sitting, supine and hyperoxic) to make a comparison between the CORIMAP prototype camera and the Oxymap T1. The ODR is inversely linear related to the oxygen saturation. Therefore, the oxygen saturation can be determined in the retinal vessels.

Secondary outcome

The secondary study parameter is the measurements of the prototype CORIMAP camera and Oxymap T1 of the diameter of the vessels of the retina in both normoxia and hyperoxia.

Study description

Background summary

This study protocol is part of the ROPOXYMAP study, which has as a main goal to make retinal oximetry available for children with vascular retinal diseases. Retinal oximetry is an imaging technique, which utilizes the difference in light absorption of hemoglobin bound and unbound to oxygen at different wavelengths of light, to determine the relative oxygen saturation of the blood in the retinal vessels.

The Compact Retinal Mapper (CORIMAP) camera has been developed to make retinal oximetry available for the use in infants, in order to gain knowledge about the oxygen metabolism of the retina in premature born children with a risk of developing ROP. The available Oxymap T1 oximeter is only suitable for oxygen saturation measurements in adults. Currently, there is no objective way to measure the relative oxygen saturation in the retinal vessels in this vulnerable group of patients. With the introduction of the CORIMAP, this

imaging technique will provide an increase in the insight of the oxygen metabolism of the retina. There are creating possibilities for improving the management, treatment and even prevention of ROP.

A second beneficial advantage of this newly developed device, is its non-invasive approach to acquiring the fundus images in supine infants without making contact to the superficial layer of the eye (cornea). This is in contrast to the current standard camera for neonatal screening (RetCam, Clarity, USA), which needs to make contact to the cornea to acquire images. Additional advantage that exceeds from neonatal care into adult care is the possibility to capture images in supine position, which is beneficial to patients who cannot be seated in front of a conventional fundus camera, such as severely ill or (sub)comatose patients.

With this study protocol, we wish to introduce a prototype handheld camera with oximetry abilities, called the CORIMAP camera. Before making the transition to an infant/child population, this study aims to validate and calibrate the CORIMAP camera in comparison to the current Oxymap T1 in a healthy adult population.

Study objective

The primary objective of this study is to determine the Optical Density Ratio (ODR) for the prototype CORIMAP camera and compare the ODR values with the Oxymap T1 mounted on a regular fundus camera in a healthy adult population. For comparison, it is paramount to determine the ODR of both oximeter cameras in normoxia and hyperoxia conditions. With this study protocol, we wish to introduce a prototype handheld camera with oximetry abilities, called the CORIMAP camera. This study aims to validate and calibrate the CORIMAP camera in a healthy adult population.

Study design

The study design is a prospective intervention study of healthy volunteers. The volunteers will be recruited during a period of a year at the outpatient clinic of the department of ophthalmology of the Leiden University Medical Centre.

For this study, a prototype handheld fundus camera with retinal oximetry functionality will be used to acquire retinal images. The oximetry functionality will be tested and compared to the validated Oxymap T1 (commercial available oximeter) with in normoxia oxygen breathing and in hyperoxia condition by the supplication of oxygen. The validation study of the Oxymap T1 used a study design, similar for the current study for the validation of the CORIMAP camera. The prototype camera will be the first handheld oximeter; therefore the repeatability will be tested in the handheld mode (supine) as well as mounted in an ophthalmologic chin rest for seated patients.

Intervention

The purpose of a retinal oximeter is the measure the relative oxygen saturation in the retinal vessels. Therefore, measuring oxygen saturation in different oxygen conditions (normoxia / hyperoxia) is paramount determining the sensitivity of the measurements of the CORIMAP camera.
In one of the three phases of the photo session, participants will be supplied with 100% oxygen, isocapnic until hyperoxia is reached. This procedure will be repeated for both oximeter cameras. During this stage, an arterial line wil be inserted in the participants for monitoring the bloodgas values. During the recovery phase, retinal images will be captured every 15s during a period of 3 min. The pupil of one of the eyes of the participants will be dilated with 1 drop Tropicamide 0.5% during the ophthalmological examination for the duration of the study procedure/

Study burden and risks

The volunteers participating in this study will visit the outpatient clinic of the department of ophthalmology, the LUMC once for this study. The visit will take between 90-120 minutes. During this visit, the participants will undergo an ophthalmological examination and a photo session. This photo session consists of three phases (sitting up right (both oximeters)), supine position (CORIMAP camera) and hyperoxic 100% (both oximeters). During the hyperoxia experiment a member of the department of Anaesthesiology will be present to insert an arterial line, for verifying the blood gas values to ensure that hyperoxia has been reached and to monitor the subjects during the experiment. The benefits of the arterial line for collecting data from blood gas values outweighs the small risk of complications.

The risk of the instilment of the mydriatic drops is equal to the minimal risks of a regular visit to the ophthalmologist. As for the prototype camera, all technical specifications are well within the NEN*EN-ISO 15004-2-2007 guidelines, therefore risks should be equal to regular ophthalmological fundus cameras. The oximetry functionality of the CORIMAP camera will be beneficial for adults in supine position and young children, especially for premature born children. This latter fragile population is at risk of developing retinopathy of prematurity. Present study will precede a study in infants, with as goal to perform retinal oximetry in (premature) infants. These studies individual and combined will provide a better understanding in the physiology of the retinal metabolism and understanding of pathophysiology in retinal diseases to create possibilities for early detection, treatment, management and even prevention.

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

Participants with an age between 18 - 35 years

Exclusion criteria

• Subjects will be excluded in case of pathological findings during the ophthalmologic examination incl. ocular opacity
• Subjects will be excluded if refractive error is lagers than +/- 6.00 dioptres and / or a cylinder of +/- 1.50 dioptres
• Subjects will be excluded in case of any ocular diseases in their history or a familial history of glaucoma.
• Subjects with any systemic disease, which could affect the eye or oxygen levels such as

diabetes, respiratory- and cardiovascular disease are excluded.
• Subjects are excluded if they smoke

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):	09-07-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Corimap Camera - Compact Oximetry Retinal Imager for Premature infants Camera
Registration:	No

Ethics review

Approved WMO

Date:	10-05-2016
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

ID: 27289
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56086.058.16