A Comparison between a prototype, mobile, handheld retinal oximeter and the current "gold standard" the Oxymap T1

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27289

Source
Nationaal Trial Register

Brief title
CORIMAP study

Health condition

Retinopathy of Prematurity, Retinal diseases

Sponsors and support

Primary sponsor: Leiden University Medical Centre
P.O. Box 9600
2300 RC Leiden
The Netherlands
Source(s) of monetary or material Support: Stichting ODAS, Stichting LOOF

Intervention

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 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 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.

The study design is a prospective intervention study of healthy volunteers. In these healthy volunteers the ODR will be determined with a prototype mobile handheld oximeter and the current Oxymap T1 oximeter in two different positions as well as different breathing circumstances (normoxia and hyperoxia).

Recruitment will be at the Leiden University Medical Centre. The study population consists of

healthy volunteers in the age range of 18 - 35 years of age.

The pupil of one of the eyes of the participants will be dilated with 1 drop Tropicamide 0.5% during the ophthalmological examination. 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. An arterial line will be inserted in the last fase of the study procedure to monitor the blood gas values during

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

This study protocol 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.

Study design

The volunteers participating in this study will visit the outpatient clinic of the department of ophthalmology, the LUMC
once for this study.

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

Contacts

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Eligibility criteria

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, respiratoryand
cardiovascular disease are excluded.

• Subjects are excluded if they smoke

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2016
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-01-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43401
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6721
NTR-old	NTR6932
CCMO	NL56086.058.16
OMON	NL-OMON43401

Study results