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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

# Samenvatting

### ID

NL-OMON27289

Bron NTR

Verkorte titel CORIMAP study

#### Aandoening

Retinopathy of Prematurity, Retinal diseases

### Ondersteuning

Primaire sponsor: Leiden University Medical Centre
P.O. Box 9600
2300 RC Leiden
The Netherlands
Overige ondersteuning: Stichting ODAS, Stichting LOOF

### **Onderzoeksproduct en/of interventie**

### Uitkomstmaten

#### Primaire uitkomstmaten

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.

# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

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.

#### Doel van het onderzoek

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.

#### Onderzoeksopzet

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

#### **Onderzoeksproduct en/of interventie**

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

# Contactpersonen

#### **Publiek**

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Leiden 2333 ZA The Netherlands 071 5297433

### Wetenschappelijk

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# **Deelname eisen**

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Participants with an age between 18 - 35 years

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

4 - A Comparison between a prototype, mobile, handheld retinal oximeter and the curr ... 4-05-2025

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

# Onderzoeksopzet

### Opzet

Туре:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	13-07-2016
Aantal proefpersonen:	30
Туре:	Verwachte startdatum

# **Ethische beoordeling**

Positief advies Datum: Soort:

02-01-2018 Eerste indiening

5 - A Comparison between a prototype, mobile, handheld retinal oximeter and the curr ... 4-05-2025

# Registraties

# **Opgevolgd door onderstaande (mogelijk meer actuele) registratie**

ID: 43401 Bron: ToetsingOnline Titel:

# Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

# In overige registers

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

# Resultaten