ROPCORIMAP - Retinal Oximetry in Retinopathy of Prematurity with the Compact Retinal Mapper Camera

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The objective of this pilot study is to measure the ODR of the retinal vessels in infants at risk of developing ROP. The secondary objective is to measure the vessel diameter of the retinal vessels in infants at risk of developing ROP

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON47202

Source
ToetsingOnline

Brief title
ROPCORIMAP

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retinal disease of the prematurely born infant) Coats Disease (exudative retinitis, retinal vessel dilations), Retinopathy of prematurity (ROP

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Stichting ODAS

Intervention

Keyword: Pediatric Ophthalmology, Retinal Imaging, Retinal Oximetry, Retinopathy of prematurity

Outcome measures

Primary outcome

The main study parameter will be the ODR of the retinal vessels of premature

born infants. The ODR of the retinal vessels will be compared per infant as

well as between infants for those who develop ROP and those who do not

Secondary outcome

The second study parameter will be de vessel diameter of the retinal vessels.

Study description

Background summary

Retinopathy of prematurity (ROP) is a potential blinding disease of premature born infants. Oxygen plays a pivotal role in the pathophysiology of ROP. With the introduction of retinal oximetry for infants, this pilot study aims to increase the insight into the oxygen metabolism of the developing retina of premature born infants. Retinal oximetry utilizes the difference in light absorption of hemoglobin bound and unbound to an oxygen molecule for measurement of relative oxygen saturation within the retinal vessels. With the introduction of the newly developed CORIMAP retinal oximeter, dual wavelength retinal oximetry has become available for use in preterm infants to monitor the oxygen saturation in the retinal vessels.

Study objective

The objective of this pilot study is to measure the ODR of the retinal vessels in infants at risk of developing ROP. The secondary objective is to measure the vessel diameter of the retinal vessels in infants at risk of developing ROP

Study design

This prospective cohort pilot study will be performed at the Neonatal Intensive Care Unit of the department of Neonatology of the LUMC. This imaging study will

be incorporated in the current ROP screening program according to the Dutch ROP guideline to minimize the burden for the infants. After approval and the initial start of this study the duration will be until 30-50 infants are included.

Study burden and risks

The benefit of this study will be an increase of insight into the retinal oxygen metabolism of infants with the risk of ROP with non-invasive retinal oximetry imaging. The study procedure will be combined with the regular Dutch ROP screening protocol with the RetCam II, which includes the necessity of mydriasis and the use of eyelid specula.

The nature and extent of the burden of this study will be minimal, although this investigation will take place in very fragile preterm infants. The study is designed in a fashion to ensure minimal burden to this study population. The burden will consist of an extension of examination time by 10 min (and the enquiring of three extra images per eye with minimal light exposure with the non-contact CORIMAP Camera. The regular ROP screening consultation with the invasive RetCam examination (corneal contact, continuous illumination) will take up to 60 minutes, including the preparation of the infants. Therefore, the potential benefits in management, possible prevention and treatment of retinal oximetry in this fragile patient population outweigh the minimal burden of this investigation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

According tot de Dutch National ROP screening Guidelines.
Premature born infants with a gastional age < 32 weeks; birth weight <1500 gr. Or a gastional age 30-32 weeks or with a birth weight of 1250-1500 gr. with one or more of the following risk factors: artificial ventilation, Sepsis, Necrotising enterocolitis, Cardiotonics due to hypotension, Postnatal treatment with steroids

Exclusion criteria

* Opacity of ocular media
* Congenital ocular defects (cataract, colobomen, schisis etc.)
* Not stabile enough for additional imaging according to the treating physician (neonatologist)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2017

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	15-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-04-2018
Application type:	Amendment
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	NL58892.058.16