Oxymap - Analysing oxygenation of vitreoretinopathies and oxygen related disease in children.

Published: 25-11-2014
Last updated: 17-08-2024

The objective of this study is to investigate the use of retinal oximetry in children, between five and seventeen years of age, with (vitreo-) retinopathies and oxygen-related diseases of the retina by means of an Oxymap T1 fundus camera.

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

Summary

ID

NL-OMON41972

Source
ToetsingOnline

Brief title
KidOxymap

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retinal disease of the prematurely born infant) Coats Disease (exudative retinitis, retinal vessel dilations) Amblyopia (Lazy eye), 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: Amblyopia, Retinal oximetry, Retinopathy of prematurity, Vitreoretinopathies

Outcome measures

Primary outcome

The primary outcome will be the oxygen saturation level within the retinal vessels of the 1st en 2nd degree. The difference in the level of oxygen saturation of retinal blood vessels between the reference group of healthy eyes of the patients with amblyopia and Coats disease and several oxygen-related retinal diseases will be compared.

Secondary outcome

The diameter of the retinal blood vessels.

Study description

Background summary

Oxygen plays a major role in many ocular diseases in adults and children. A state of hypoxia can lead to neovascularization or abnormal vessel development under influence of Vascular Endothelial Growth Factor (VEGF). The development of neovascularizations or abnormal vessels may lead to blindness in children and adults. Abnormal vascularization of the peripheral retina and retinal detachment are common clinical characteristics of many paediatric (vitreo-) retinopathies such as Norrie disease, M. Coats, Familial Exsudative Vitreoretinopathy (FEVR) and retinopathy of prematurity (ROP). In early stages of hereditary ocular disease such as retinitis pigmentosa, it has been found that there are discreet changes to the calibers of the vessels. These caliber changes in the retinal vessels will have its effect on the oxygen metabolism of the eye. Recently, a small pilot study reported, a difference in oxygen saturation levels in the retinal vessels between the healthy eye and the amblyopic eye in patients with amblyopia.

In recent years, a retinal oximeter (Oxymap) has become available for clinical and investigational use. The Oxymap application is attached to a regular clinical Topcon fundus camera and it uses two different wavelengths of light to

image the fundus of the eye; one wavelength is sensitive to changes in oxygen saturation, the other wavelength is not. The algorithm of the Oxymap software calculates the relative oxygen saturation in all major arterioles and venules of the retina; comparisons can be made between vessels as well as in time. The Oxymap has been used to investigate various diseases in adults, such as diabetic retinopathy, retinal vein occlusion, glaucoma and radiation retinopathy in melanoma of the eye. In a pilot study in Reykjavik, a difference was found between saturation levels within the vessels of the eye between adults and children. However, knowledge about retinal oximetry in children is very limited.

Study objective

The objective of this study is to investigate the use of retinal oximetry in children, between five and seventeen years of age, with (vitreo-) retinopathies and oxygen-related diseases of the retina by means of an Oxymap T1 fundus camera.

Study design

This study is a prospective observational case series of paediatric patients diagnosed with (vitreo-) retinopathies and oxygen-related diseases of the retina. Patients visiting the outpatient department of ophthalmology that will need fundus imaging (normally 15-20 images) will be asked to participate in this study. As part of the regular examination, children visiting the clinic with one of the conditions mentioned above will receive mydriatic eye drops from their ophthalmologist to dilate their pupils. After the infant and his or her legal guardian(s) are informed, in word and written text, and have given informed consent, we will obtain additional fundus images (five images) for Oxymap research purpose. In regular follow-up consultation for the subjects, we will ask the subjects for additional Oxymap images to follow up treatment as well as disease of the eye. As pupils are already dilated, there are no additional risks for the patients concerning participation in the study. All images will be obtained in regular consultations; patients will not be asked to make extra visits

Study burden and risks

For this study de burden and risks associated with the participation are minimal due to the fact that all subjects will be recruited from ophthalmologic consultation with dilation of the pupils therefore no additional medication is required for study purposes. The additional time burden will take about 15-25 minutes per session and can be incorporated in to routine fundus photography.

Results of this study will be beneficial for the children with retinal disease because at this point data is limited and much can be gained. A better

understanding of retinal oximetry in children with retinal disease will possibly lead to better treatment modalities, management and even prevention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Subjects between 5 - 17 years of age
- Subjects with (vitreo-) retinopathies like Retinopathy of prematurity, Coats disease, FEVR, Norries disease
- Subjects with Amblyopia
- Subjects with Retinititis pigmentosa

Exclusion criteria

- Subjects with below age 5 and above 18 years of age
- Subjects with ocular opacity
- Subjects with Insufficient dilation of pupils after administering mydriatica
- Subjects with retinal detachment.
- Subjects unable to cooperate

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	25-11-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-07-2015
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	NL50768.058.14