Oxymap - Analysing oxygenation in treated and untreated vitreoretinopathies and oxygen related diseases in adults.

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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-OMON42158

Source
ToetsingOnline

Brief title
AdultOxymap

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retiinal vessel dilations; Amblyopia (Lazy eye), retinal disease of the prematurely born infants; Coats (exudative retinitis, 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;Nederland

Intervention

Keyword: Amblyopia, Retinal oximetry, Retinopathy of prematurity, Vitreoretinopathies

Outcome measures

Primary outcome

Primary outcome will be the oxygen saturation measurements of the retinal

arteries and venules of the 1st and 2nd degree.

Secondary outcome

Secondary outcome will be the arterial en venular vessel diameter measurements.

The increased understanding of the mechanisms of ophthalmic diseases will

improve management of the disease, making earlier detection possible and

increasing treatment modalities.

Study description

Background summary

The oxygen metabolism of the retina plays a key role in many ocular diseases in children and adults. Imbalance between the retinal demand and the supply of oxygen to the retina may lead to ischemia. This will stimulate the production of vasoactive factors such as Vascular Endothelial Growth Factor (VEGF) resulting in neovascularisation. These newly formed vessels are of bad quality not only leading to subretinal leakage of fluid and protein but also to insufficient oxygen distribution to the retina. Ocular diseases in which the oxygen metabolism plays an important role in their aetiology have a major contribution to visual impairment or blindness. Some of these ocular diseases develop shortly after birth or in early childhood, for example Coats disease and retinopathy of prematurity (ROP). Even after successful treatment at an early stage, these diseases can re-activate in adulthood. Although it is known that oxygen plays a major role in the development of these diseases, the exact

aetiology is not fully understood.
Furthermore, a recent pilot study has shown that oxygen saturation levels in the retinal vessels are decreased in amblyopic eyes, in contrast to their healthy, non-amblyopic eyes. This indicates that the oxygen metabolism might also play a role in the development of amblyopia. Therefore, a better understanding of the oxygen-metabolism of the eye in these specific diseases will lead to an increased insight, thereby improving their management and making early detection of re-emerging disease possible. Since recent years, non-invasive retinal oximetry has become available to measure the relative saturation levels in the retinal blood vessels.

The retinal oximetry
These non-invasive retinal oximeters measure the relative oxygen saturation levels in the blood vessels of the retina by means of different wavelength imaging. The Oxymap T1 is developed by the University of Reykjavik; this instrument uses two different wavelengths of light (570nm and 600nm) to capture images. The difference in the light reflection of the oxyhaemoglobin in the arteries (highly oxygenated) and the deoxyhaemoglobin in the venules (less-oxygenated) allows for measurements of the oxygen saturation of the retinal vessels by means of a (Oxymap) software algorithm. This algorithm calculates the optical density (OD) derived from both fundus images, resulting in a pseudocolor map of the oxygen saturation levels of the blood vessels in a fundus image

Study objective

The objective of this study is to analyse the retinal oxygenation in adults with the Oxymap T1 in patients with amblyopia and untreated or treated (vitreo-) retinopathies and compare them to a reference group of healthy eyes of amblyopic and Coats patients.

Study design

This study is a prospective observational case series of adult patients with oxygen-related ocular diseases. Eligible patients will be invited by the treating ophthalmologist or (sub) investigator to participate in the study. When possible, all images will be obtained during regular consultation of the patients at the outpatient clinic of the department of ophthalmology of the LUMC. However, adult patients with (un)treated ROP and Coats disease are scarce in number and frequency of regular consultations is low. Patients will be invited in writing if there is no consultation scheduled at the department of Ophthalmology of the LUMC within a reasonable timeframe. In case of a writing invitation for participation of the study, the additional visit will replace their regular upcoming visit. The imaging protocol requires four additional Oxymap images apart from the standard fundus images taken at regular consultations. The Oxymap imaging will be combined with the regular

ophthalmological consultations. Therefore, the patients will be followed during the research period with multiple imaging sessions.

Study burden and risks

There are no additional risks. Dilation of the pupils is part of the routine ophthalmological examination. Patients with Coats disease and (treated) ROP need regular consultations, mostly on a yearly basis. If patients consent with an additional ophthalmologic consultation with fundus images and additional Oxymap images, they will receive a full routine ophthalmologic consultation. During a routine ophthalmologic consultation pupils are dilated with mydriatica. The risk of side effects of these mydriatica is extremely low Patients with the studied diseases can benefit greatly from the obtained insight in their disease, due to the implications this might have for early detection of recurrences and possible treatment.

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

This study will include adult patients with treated (vitreo-) retinopathies (such as M. Coats, familial exsudative vitreoretinopathy (FEVR) and retinopathy of prematurity) and oxygen-related diseases (such as amblyopia).

Exclusion criteria

The exclusion criteria for participation are impossibility to obtain useful images for example caused by severe nystagmus, opacities of the ocular media, total retinal detachment or insufficient dilation of the pupils after administering mydriatic eye drops.

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):	01-06-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	27-02-2015
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

No registrations found.

In other registers

Register	ID
CCMO	NL50773.058.15