Functional Retinal Imaging of Inherited Retinal Diseases

Published: 10-01-2013
Last updated: 26-04-2024

The goal of this study is the development of a clinically verified functional imaging technique of the retina.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Eye disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON37165

Source
ToetsingOnline

Brief title
Functional imaging of RD

Condition

- Eye disorders congenital
- Congenital eye disorders (excl glaucoma)

Synonym
cone-rod dystrophy, 'inherited retinal diseases', Leber congenital amaurosis, retinitis pigmentosa, Stargardt disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Foundation Fighting Blindness

Intervention

Keyword: Dystrophies, Functional, Imaging, Retinal

Outcome measures

Primary outcome

Identification and classification of optical features that indicate the

functionality of the retina in healthy individuals and in patients with retinal

dystrophies.

Secondary outcome

Not applicable.

Study description

Background summary

Retinal dystrophies represent a group of inherited ophthalmic diseases, which are characterized by progressive dysfunction or loss of retinal photoreceptor cells, often accompanied by fundus abnormalities. Retinal dystrophies represent the most important cause of juvenile blindness in the Western world for which no treatment is currently available. Although gene-therapy treatments for retinal dystrophies are currently being developed, clinical characterization of these diseases is largely based on assessments with a strong subjective component, poor sensitivity, and poor resolution. Therefore there is a growing demand to improve current examination techniques, in order to find out which patients may be amenable for such treatments. Recent advances in retinal imaging techniques have increased the abilities of clinical characterization, including the accurate monitoring of disease progression and detection of remaining functional retina in retinal dystrophies. While currently available devices only allow for morphological retinal imaging, imaging of photoreceptor function has been shown to be feasible in several studies. This innovative functional retinal imaging provides the opportunity to observe retinal function on a micrometer scale, which will be of great significance for patient selection for, and documentation of future gene-therapeutic studies.

Study objective

The goal of this study is the development of a clinically verified functional

imaging technique of the retina.

Study design

Prospective case-control study.

Study burden and risks

Participants do not benefit at the time of the study. All procedures are non-invasive and there are no significant risks known about the examination techniques applied in our study. The additional time spent for study investigations will be about one hour.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Philips van Leydenlaan 15
Nijmegen 6500 HB
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Philips van Leydenlaan 15
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Patients recruited from the RP5000 study (see Onderzoeksprotocol, page 7 + 8) with one of the following non-syndromic retinal dystrophies: Retinitis pigmentosa, Leber congenital amaurosis, Stargardt disease or cone-rod dystrophy.
-Healthy independent volunteers with normal retinal functionality.
-All study participants are of mature age and of sound mind and judgement.
-Both eyes are able to fixate adequately for the imaging procedure.
-Absence of cataract in both eyes.

Exclusion criteria

Healthy volunteers and patients, who do not meet the inclusion criteria.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	10-01-2013
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL40790.091.12