Study on test-REtest reliability in Patients with inheritEd retinAl dysTrophies (REPEAT study)

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Our study objective is to investigate the reliability of commonly used clinical examinations and endpoints performed in patients with inherited retinal dystrophies in anticipation of future clinical trials.

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-OMON51638

Source
ToetsingOnline

Brief title
REPEAT study

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
inherited retinal dystrophy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: inherited retinal dystrophy, microperimetry, test-retest variability

Outcome measures

Primary outcome

The main parameter is the test-retest variability in microperimetry, demonstrated as the change average threshold (dB) between two repeated measurements of macular sensitivity.

Secondary outcome

Secondary endpoints include the changes in other functional and structural outcome measures between repeated measurements. The functional measures include the test-retest variability of best-corrected visual acuity under different light intensities, visual field, fixation stability, and reported quality of life. The structural parameters include test-retest variabilities of parameters measured on SD-OCT and fundus autofluorescence.

Study description

Background summary

Inherited retinal dystrophies (IRDs) encompass a spectrum of severe eye diseases, characterized by progressive loss of retinal structure and visual function. No treatment is currently available for the majority of IRDs, although promising results have been achieved using gene therapy in one specific type of IRD, paving the way for future treatment. However, there is a knowledge gap on which clinical investigations and endpoints are most suitable to test treatment efficacy. Particularly, little is known on test-retest variability in this patient group for a range of specialized clinical examinations that appear important for the evaluation of these diseases. This information appears pivotal for optimal patient selection, and to determine reliable clinical parameters for upcoming clinical trials focused on treatments. Therefore, further insight is required into the reliability of

commonly used clinical outcome measures such as microperimetry, full-field stimulus threshold testing, perimetry, best-corrected visual acuity, and retinal structures on multimodal imaging. Determining the test-retest variability of these outcome measures will aid future trials in distinguishing treatment efficacy from measurement errors.

Study objective

Our study objective is to investigate the reliability of commonly used clinical examinations and endpoints performed in patients with inherited retinal dystrophies in anticipation of future clinical trials.

Study design

Investigator-initiated, single-center, prospective, observational study consisting of two visits over a two-week (± 2 week) interval. During each visit, the participants will perform several ophthalmological measurements.

Study burden and risks

No interventional therapy or study drug will be used and thus there is no risk of adverse events. However, patients (especially young children and elderly) may experience a minimal physical burden of visiting the hospital twice in two weeks. Additionally, patients may feel confronted with their visual impairments. Lastly, the use of mydriatics pose a minimal risk of acute angle closure glaucoma. In order to prevent this, the ocular pressure will be strictly monitored during the study and potential occurrence of an increase in pressure will be treated according to standard clinical protocol. These burdens are expected to be minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study as a visually-impaired patient, a subject must meet all of the following criteria:
• Willing and able to provide informed consent (IC) for the participation in the study;
• Minimum age of 16 years;
• Clinical diagnosis of IRD with BCVA using ETDRS of >=20/50 Snellen equivalent;
• Willing and able to undergo ophthalmic examinations at two separate occasions;
• No ocular or non-ocular disease/disorder that may influence the results of the measurements.

In order to be eligible to participate in this study as a low-vision patient, a subject must meet all of the following criteria:
• Willing and able to provide informed consent (IC) for the participation in the study;
• Minimum age of 16 years;
• Clinical diagnosis of IRD with BCVA using ETDRS of <20/50 Snellen equivalent;
• Willing and able to undergo ophthalmic examinations at two separate occasions;
• No ocular or non-ocular disease/disorder that may influence the results of the measurements

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• The last measured BCVA in the better-seeing eye is light-perception;
• (History of) ocular of non-ocular disease/disorder that may influence the

results of the measurements (e.g. amblyopia);
• Known allergy or intolerance for ocular anesthetic eye drops oxybuprocaine 0.4% or mydriatics tropicamide 0.5% and/or phenylephrine 5%;
• Participation in another research study involving an investigational medicinal product related to their ocular health.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2022
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	10-05-2022
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	NL79646.058.21