Prospective clinical evaluation of inherited retinal diseases

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The use of structural biomarkers (e.g. fundus autofluorescence imaging, optical coherence tomography or a combination thereof) may show a much more gradual progression that is indicative of functional vision loss at a later stage.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20528

Bron
Nationaal Trial Register

Verkorte titel
IRD prospective

Aandoening

Inherited retinal diseases, Stargardt disease, retinal dystrophy
Erfelijke netvlies aandoeningen, de ziekte van Stargardt, netvliesdystrofie

Ondersteuning

Primaire sponsor: Radboud University Medical Center
Overige ondersteuning: Foundation Fighting Blindness

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Best corrected visual acuity, quantitative fundus autofluorescence intensity data, mean

retinal sensitivity as measured by fundus-guided microperimetry, ellipsoid zone area as measured by SD-OCT, visual field sensitivity measured by static perimetry, macular and retinal function using multifocal and full-field ERG amplitudes and implicit time, rod and cone full-field stimulus thresholds.

Toelichting onderzoek

Achtergrond van het onderzoek

The vast majority of inherited retinal diseases are not yet treatable and therefore patients generally have not been examined at short intervals. However, trials on therapies for IRDs are upcoming, and to assess effectiveness of such therapies we need detailed knowledge on the natural course of these diseases as well as identification of clinical biomarkers of disease progression. The goal of this study is to characterize the natural course of IRDs that can potentially be modulated by future therapy. Second, this study aims to understand the relationship between various structural and functional biomarkers in potentially therapy-eligible IRD cases which could ultimately lead to the acceptance of structural biomarkers as clinical endpoints.

Doel van het onderzoek

The use of structural biomarkers (e.g. fundus autofluorescence imaging, optical coherence tomography or a combination thereof) may show a much more gradual progression that is indicative of functional vision loss at a later stage.

Onderzoeksopzet

Baseline, 6mnths, 12mnths, 18mnths, 24mnths 30mnths, 36mnths.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Cohort-specific inclusion criteria:

- Clinical diagnosis of STGD and at least two pathogenic or likely pathogenic, therapy-eligible mutations in trans in the ABCA4 gene

Participants must meet the following:

- Age =/> 12 years

- Willing and able to complete the informed consent

- Ability to return for all study visits over 36 months

Both eyes of participants must meet the following:

- Baseline visual acuity ETDRS letter score of 54 or more (approximate Snellen equivalent 20/80 or better)

- Stable fixation and ability to perform perimetry reliably

- Clear ocular media and adequate pupil dilation to permit good quality imaging

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- Mutations in genes that cause autosomal dominant or X-linked retinal dystrophy, or presence of biallelic mutations in autosomal recessive retinal dystrophy genes other than the gene studied in the patient cohort

If either eye has any of the following, the patient is not eligible:

- Current vitreous hemorrhage

- Current or any history of rhegmatogenous retinal detachment

- Current or any history of (e.g., prior to cataract or refractive surgery) spherical equivalent of the refractive error worse than -8 Diopters of myopia

- History of intraocular surgery (e.g., cataract surgery, vitrectomy, penetrating keratoplasty, or LASIK) within the last 3 months

- Current or any history of retinal vascular occlusion or proliferative diabetic retinopathy

- Expected to have cataract removal surgery during the study

- History or current evidence of ocular disease that, in the opinion of the investigator, may confound assessment of visual function

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	40

Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48655
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6948
NTR-old	NTR7204
CCMO	NL65175.091.18
OMON	NL-OMON48655

Resultaten