Caucasian high and pathological myopia: a prospective longitudinal study

Published: 06-12-2019
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To study the progression of high and pathologic myopia over time.

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-OMON48506

Source
ToetsingOnline

Brief title
Caucasian high myopia

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
High myopia

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Landelijke Stichting voor Blinden en Slechtzienden & Uitzicht

Intervention

Keyword: Caucasion, High myopia, Ocular comorbidities, Retinal anatomy

Outcome measures

Primary outcome

Progression of myopia/myopic maculopathy.

Secondary outcome

Visual acuity, axis length, visual field, OCT (retinal anatomy).

Study description

Background summary

Pathologic myopia is a type of high myopia that is characterized by the presence of chorioretinal atrophy, staphylomas and/or choroidal neovascularization. These abnormalities make pathologic myopia one of the main contributors to impaired vision and blindness worldwide. Our understanding of high and pathologic myopia is mainly based on large follow-up studies from Asian countries. It is unclear whether the knowledge obtained from Asian studies also applies to Caucasian patients. From clinical experience, it seems that Caucasian high and pathologic myopia acts differently from the described Asian studies. For example, in Asia most patients with a myopic choroidal neovascularization only need one anti-VEGF injection. While in contrast, most Caucasian patients need more injections and have frequent recurrences.

Study objective

To study the progression of high and pathologic myopia over time.

Study design

Prospective, longitudinal study

Study burden and risks

This is an observational study, risks are negligible, burden is moderate. Duration of the study is 3 years and involves 6 visits to the REH. Two visits take about 1 hour each, the other four visits will take 3 hours each.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age >= 40 years;
Highly myopic refractive error
Caucasian background.

Exclusion criteria

Visual acuity > 0.7 logMar at baseline
Ocular media of inadequate clarity to permit high quality fundus imaging
Previous ocular trauma
Keratoconus

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-02-2020
Enrollment:	120
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	06-12-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL71597.078.19