Dissection of the etiology of myopia and efficacy and safety of an Artisan phakic iris-claw intraocular lens for the correction of high myopia

Published: 29-10-2009
Last updated: 17-08-2024

Dissection of etiology of myopia- identification of genetic risk factors- identification of environmental risk factors- evaluation of the long term safety of Artisan phakic intraocular lenses for the correction of high degree myopia

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON45140

Source
ToetsingOnline

Brief title
myopia study, MYST

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
high myopia, severe nearsightedness

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: NWO/VIDI;NWO/VICI;NWO/VENI subsidie; ERC-consolidator grant,patientenverenigingen (o.a. Uitzicht)

Intervention

Keyword: epidemiology, genetics, myopia, nearsightedness

Outcome measures

Primary outcome

Primary study parameters:

- Single nucleotide polymorphisms (SNPs) or mutations

Primary outcome variable:

- High myopia present/absent

Secondary outcome

Secondary study parameters:

- environmental risk factors such as reading in youth, education, refractive

error of parents etc

- range of accommodation

Secondary outcome variable:

- refraction as continuous variable

- axial length

- cornea curvature, anterior chamber length

- complications of myopia such as glaucoma, retinal defects, staphyloma and

macular degeneration

- safety of phakic Artisan intraocular lenses

Study description

Background summary

Myopia, or shortsightedness, is a frequent eye disorder that may lead to blindness. There are currently no treatment options to stop progression or cure the complications. The many animal studies on this topic have not revealed the causes of myopia in humans. From epidemiologic studies it has become clear that the disease is highly heritable. The current hypothesis is that myopia is a complex genetic disorder probably consisting of multiple genes with relatively small effect. Therefore, large studies with substantial statistical power are needed.

Study objective

Dissection of etiology of myopia
- identification of genetic risk factors
- identification of environmental risk factors
- evaluation of the long term safety of Artisan phakic intraocular lenses for the correction of high degree myopia

Study design

This study will consist of 600 subjects with high myopia (more than -6 diopters), 600 control subjects, and 150 family members of cases with high myopia. All subjects will undergo a complete ophthalmologic examination including visual acuity, refractive error, axial length, keratometry, stray light measurement, anterior segment analysis (cornea cell count and position of implant lens), photography of the retina, and an OCT (measures thickness of the retina). We will elucidate family pedigrees, draw blood for DNA analysis, and use a questionnaire to ask about course of progression and environmental factors (education, socio-economic status, occupation, smoking, diet, reading habits and outside activities in youth).

Study burden and risks

The time investment and the effects after mydriasis of the pupils form the most important burden.

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

Persons aged 18 years or older, high myopic from SE -6D and higher, and persons with SE -1.5 D to +1.5 D.

Exclusion criteria

younger then age 18; refractive error between SE -1.5 D and -5.75 D; or refractive error SE > 1.5 D

Study design

Design

Study type:	Observational 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):	07-12-2009
Enrollment:	1400
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-02-2018
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	NL28647.078.09