Influence of multifocal intraocular lens on standard automated perimetry

Published: 01-02-2012
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To determine the influence of MFIOL on standard automated perimetry.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON37804

Source
ToetsingOnline

Brief title
Influence of multifocal intraocular lens on perimetry

Condition

- Glaucoma and ocular hypertension

Synonym
Implants, Multifocal intralocular lens

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Glaucoma, Multifocal intraocular lens, Perimeter

Outcome measures

Primary outcome

To determine the influence of MFIOL on standard automated perimetry test

results with the default stimulus size (size III).

Secondary outcome

To study the effect of a larger stimulus size (size V). Here the hypothesis is

that a larger stimulus is less prone to optical imperfections (like that of a

MFIOL).

Study description

Background summary

The aim of this study is to investigate the influence of multifocal intraocular lenses (MFIOL) on standard automated perimetry (SAP). SAP is the main test for the diagnosis and the follow-up of glaucoma, a progressive eye disease that may result in blindness if left untreated. SAP measures contrast sensitivity which declines due to both glaucoma and age, the latter through age-related changes in the eye optics and retinal aging.
In young eyes, crystalline lenses are clear, flexible and can accommodate to focus on images nearby and in a distance. Later on, accommodation is no longer possible and reading glasses are needed. MFIOL is nowadays more frequently implanted after cataract extraction to avoid the need of reading glasses. A major drawback of the MFIOL, however, is loss of contrast sensitivity. As the prevalence of MFIOL will increase in time, we need to know how this new lens influences SAP, in order to be able to diagnose and monitor glaucoma in patients with a MFIOL.. Therefore, the aim of this study, described in this protocol, is to compare age-matched normative perimetry data of healthy subjects with subjects with a MFIOL implant.

Study objective

To determine the influence of MFIOL on standard automated perimetry.

Study design

Case-control study

Study burden and risks

A single visit in which SAP is performed and a few additional tests to verify the healthy state of the eye. Total time investment 1 hour. It is possible that an eye disease will be discovered during the course of this study. The resulting psychological distress for the subject can be a disadvantage. However, the advantage can be an earlier adequate treatment. All the measurements are performed with optical techniques which do not touch the eye and are therefore completely harmless and thus there is no risk during the experiments. No mydriasis (pupil dilatation) will be performed.

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

Human subjects aged 18 and above, with a maximum of 70 years, who are able and willing to participate in this study

Exclusion criteria

Best correct visual acuity (BCVA) of <0.8 or <0.67 when aged above 50
Repeatable visual field defects detected with perimetry

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2012
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-02-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	26-02-2014
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL39274.042.11