Influence of multifocal intraocular lens on glaucoma diagnostic tests

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To determine the influence of MFIOL on glaucoma diagnostic tests namely, the FDT, OCT, and GDx.

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

Summary

ID

NL-OMON40755

Source
ToetsingOnline

Brief title
multifocal intraocular lens and glaucoma tests

Condition

- Glaucoma and ocular hypertension

Synonym
implants, Multifocal intraocular 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: Diagnostic tests, Glaucoma, multifocal intraocular lens

Outcome measures

Primary outcome

FDT: number of abnormal test locations;

OCT: thickness of the retinal nerve fibre layer (RNFL) and the retinal ganglion

cell layer (RGCL);

GDx: the nerve fibre index

Secondary outcome

Not applicable.

Study description

Background summary

Ever since 2006, multifocal intraocular lenses (MFIOL) are being implanted after cataract extraction to free patients from reading spectacles by applying the principle of simultaneous vision. However, the design needed to provide such optical luxury causes at the same time a reduction in the contrast sensitivity of the eye. Reduction in contrast sensitivity is normally seen in aging eyes and is also a typical sign of glaucoma eye disease.

Glaucoma is a chronic-progressive disease inducing visual field defects and, if left untreated, may lead to blindness. The peripheral visual field gets affected in the early stage of glaucoma, worsening slowly while staying unnoticed for patients. Only after large parts of the visual field are affected it becomes symptomatic. Therefore diagnosing and monitoring glaucoma needs to be accurate and reliable to identify visual field defects or detect progression. Currently, standard automated perimetry (SAP) is the gold standard for this in routine clinical practice. SAP measures the retinal contrast sensitivity of the eye within the visual fields of patients.

A previous study proved however that (SAP) test results are negatively affected by the optical design of MFIOLs and may therefore, hinder early detection and optimal glaucoma care. Therefore, we would like to evaluate whether other relative glaucoma tests are eventually less affected by the optics of the MFIOL and at the same time reliable enough to ensure, when necessary, optimal glaucoma care within the group of patients implanted with MFIOLs. Frequency doubling perimetry (FDT), optical coherence tomography (OCT), and the laser

polarimetry (GDx) are the three tests mainly used in our clinic besides the SAP to detect visual field defects and assess function and anatomy of the optic nerve head and are therefore the tests we intend to evaluate.

Study objective

To determine the influence of MFIOL on glaucoma diagnostic tests namely, the FDT, OCT, and GDx.

Study design

This study has a case series design. MFIOL cases will be compared to the normative data of the included tests.

Study burden and risks

A single visit in which FDT, OCT, and GDx are performed, a questionnaire is completed 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.

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

- Patients implanted with a MFIOL aged between 18 an 70, who are able and willing to participate in this study.
- Postoperative period of at least 3 months.
- One eye will be randomly chosen and tested with the exception of the FDT. This device can only perform the test if both eyes are analysed.

Exclusion criteria

- Best correct visual acuity (BCVA) of <0.8 or <0.67 when aged above 50.
- Refractive error >±5D or a cylinder of >±2.5D.
- Intra ocular pressure (IOP) of >22mmHg.
- Optic nerve abnormalities indicating glaucoma
- Repeatable VF-defects detected with perimetry (not explained by the MFIOL in patients)
- History or current serious eye disease, trauma or surgery.

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):	25-10-2014
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2014
Application type:	First submission
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	NL48866.042.14