A randomized, subject-blinded evaluation of visual function after bilateral implantation of two types of presbyopia-correcting multifocal IOLs

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON37851

Source
ToetsingOnline

Brief title
Presbyopia-correcting multifocal IOLs

Condition

- Vision disorders

Synonym
bilateral cataract, presbyopia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: PhysIOL

Intervention

Keyword: intraocular lens implantation, presbyopia, randomized clinical trial

Outcome measures

Primary outcome

Primary outcome measure is the mean bilateral DCVA at intermediate distance (70cm) under mesopic conditions at 1, 3 and 6 months postoperatively.

Secondary outcome

Secondary outcome measures are:

*Mean unilateral UCVA at near (40cm), intermediate (70cm) and distance (4m) at photopic and mesopic conditions at 1, 3 and 6 months postoperatively

*Mean bilateral UCVA at near (40cm), intermediate (70cm) and distance (4m) at photopic and mesopic conditions at 1, 3 and 6 months postoperatively

*Mean unilateral DCVA at near (40cm), intermediate (70cm) and distance (4m) at photopic and mesopic conditions at 1, 3 and 6 months postoperatively

*Mean bilateral DCVA at near (40cm), intermediate (70cm) and distance (4m) at photopic conditions and mean bilateral DCVA at near (40cm) and distance (4m) at mesopic conditions at 1, 3 and 6 months postoperatively

*Mean contrast sensitivity monocular and binocular at photopic and mesopic conditions at 1, 3 and 6 months postoperatively

*Reading speed at photopic and mesopic conditions at 6 months postoperatively

*Mean vision-specific quality of life at 6 months postoperatively.

Furthermore, adverse events, including complications, will be reported for each

patient.

Study description

Background summary

Presbyopia is a progressive decline in the ability to focus on near objects with increasing age. Conventional management of presbyopia has been through bifocal and multifocal progressive spectacle lenses or contact lenses. Recent advances in technology have allowed surgical correction of presbyopia through intraocular lenses (IOLs) among patients undergoing cataract extraction or refractive lens exchange. Presbyopia correcting IOLs are becoming increasingly popular as they may help achieve freedom from spectacles. Two types of presbyopia correcting IOLs are the multifocal FineVision Micro F IOL and the multifocal AcrySof® IQ ReSTOR® +3 IOL.
Although the FineVision Micro F IOL has the potential to have better intermediate vision without loss of far and near vision compared to the AcrySof® IQ ReSTOR® +3 IOL, this has never been evaluated in a well-controlled, randomized, prospective study.

Study objective

The objective of this study is to prospectively evaluate postoperative visual outcomes in a series of patients bilaterally implanted with the FineVision Micro F IOL versus those bilaterally implanted with the AcrySof® IQ ReSTOR® Aspheric +3 D multifocal IOL.

Study design

The study design is a randomised clinical study to compare outcomes after implantation with the FineVision versus implantation with the AcrySof ReSTOR. A total of 28 patients will be randomised into either the FineVision group or the AcrySof ReSTOR group at a 1:1 ratio. Patients will receive standard cataract extractions with implantation of an IOL in both eyes. Patients will be examined pre-operatively and 1 week, and 1, 3 and 6 months postoperatively. The duration of the study is 15 months, based on the inclusion of patients into the RCT in the first 6 months, a follow-up of 6 months after IOL implantation and analysis of the data during the last 3 months of the study.

Intervention

The intervention will be bilateral cataract surgery with implantation of a multifocal IOL.

Study burden and risks

Patients will be followed-up according to the cataract standard of care. In addition to the standard of care, aberrometry measurements will be performed preoperatively and 1, 3 and 6 months postoperatively. Furthermore, additional visual acuity measurements, contrast sensitivity testing and reading speed test will be performed. To evaluate vision-specific quality-of-life, patient questionnaires will be used.
Patients randomized and enrolled in this clinical study have 100% assurance of having a multifocal IOL implanted into their eyes that provides the greatest likelihood of spectacle freedom following cataract extraction and IOL implantation. These lenses are not the standard of care in cataract surgery and are not reimbursed. All IOL models used in this clinical study are CE-marked and commercially available in The Netherlands. There is a possibility patients may experience a halo type effect around lights at night. Also, some patients might experience glare after surgery, which is the sensation of seeing through a foggy window. Experience with these lenses indicates that these symptoms reduce with time, but might not completely disappear. Although these lenses decrease the likelihood for spectacle wear, they do not necessary eliminate the need for them for all tasks and as such spectacles may be needed to improve vision in some instances.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

*Bilateral cataract
*Less than 1.00 diopters of corneal astigmatism in both eyes
*Fulfill the recommendations in the *Warnings* and *Precautions* sections of the AcrySof ReSTOR and FineVision package inserts*
*Age 42 years or older
*Expected postoperative logMAR +0.3 or better
*Availability to undergo second eye surgery within 2 weeks of the first eye surgery
*Willing and able to comply with scheduled visits and other study procedures
*Signed informed consent

Exclusion criteria

*Planned multiple procedures, including LRI, during cataract/IOL implantation surgery
*Previous corneal surgery and/or reshaping
Clinically significant corneal endothelial dystrophy (e.g., Fuchs dystrophy)
*History of corneal disease (e.g., herpes simplex, herpes zoster keratitis, etc.)
*Extensive age related macular degeneration (atrophic or exudative AMD or numerous soft drusen)
*Glaucoma related extensive visual field loss
*Extensive Diabetic macular disease
*Suturing of incision required at time of surgery
*Complications during surgery of the first eye.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2012
Enrollment:	28
Type:	Actual

Medical products/devices used

Generic name:	FineVision Micro F IOL / AcrySof® IQ ReSTOR® +3 D multifocal IOL model SN6AD1
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-05-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL39762.096.12