A Randomized, pilot study, subject-masked comparison of visual function after bilateral implantation of Presbyopia-correcting IOLs

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

Summary

ID

NL-OMON34149

Source
ToetsingOnline

Brief title
M10-070

Condition

- Vision disorders

Synonym
bilateral cataract, stare

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories

Source(s) of monetary or material Support: Alcon Laboratories

Intervention

Keyword: cataract visus, comparison, intraocular lens implantation

Outcome measures

Primary outcome

Primary Outcome parameter is unilateral uncorrected near visual acuity (40cm).

Secondary outcome

Exploratory outcome measurements include

- Unilateral uncorrected distance and uncorrected intermediate visual acuity

- Bilateral uncorrected distance, near and intermediate vision

- Contrast Sensitivity (unilateral and bilateral)

Range of functional vision using binocular defocus curve with best distance correction

- Reading speed

Safety parameters include any adverse events during the course of the study.

All adverse events and Alcon product related complaints will be collected at all study visits. The complete study plan is presented in table 18.1

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.

The AcrySof® IQ ReSTOR® +3 D multifocal IOL model SN6AD1 (Alcon Laboratories, Inc., Fort Worth, TX, USA) has CE certification and has been approved by the US Food and Drug Administration. This IOL has +3 D of add power at the lens plane, yielding approximately 2.5 D at the spectacle plane. The AcrySof® IQ ReSTOR® +3 D is a single piece IOL and has a 6 mm optic that consists of a central 3.6 mm apodized diffractive1 zone and an outer refractive zone. The diffractive zone facilitates near and distance vision, while the outer refractive zone facilitates distance vision without loss of light to scatter. The AcrySof® IQ ReSTOR® +3 D IOL has 9 diffractive steps and incorporates negative spherical aberration to compensate for positive corneal spherical aberration. Approximately, 8-12% of the total light is lost due to diffraction.

The LENTIS® Mplus IOL (Oculentis) has CE certification and is an aspheric refractive bifocal IOL that can be implanted into the eye through a 2.6mm incision. It is made of a hydrophilic material and is a single piece IOL that comprises a 6-mm optic with a sector shaped near vision area. This near vision area has a +3D Add that provides patients with the ability to see up close. Light is distributed asymmetrically and is dependent upon pupil size.

To date there are no well-controlled, randomized, prospective studies that compare the visual outcomes of these two different marketed lenses (Alcon AcrySof IQ ReSTOR +3 SN6AD1 and LENTIS® Mplus).

Study objective

The objective of this study is to prospectively evaluate postoperative visual outcome in a series of patients bilaterally implanted with the AcrySof® IQ ReSTOR® Aspheric +3 D multifocal IOL versus those bilaterally implanted with the LENTIS® Mplus IOL. The primary endpoint is the assessment of unilateral uncorrected visual acuity at near.

Study design

This study is a post market, subject-masked, randomized, 3 month follow up, two-arm parallel group clinical investigation to assess the superior postoperative outcomes with the AcrySof ReSTOR +3 IOL compared to LENTIS® Mplus IOL.

Intervention

An AcrySof IQ ReSTOR +3.0 D IOL or LENTIS® Mplus IOL, depending on randomization, will be implanted into the posterior capsule of the first operative eye (surgeon*s discretion).

Study burden and risks

Removal of the crystalline lens is a delicate but generally safe operation. There are no added risks compared to the standard operation just because of this implant.

There is a possibility to 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 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.

After some of the visits patients are not able to drive a car temporarily.

Disadvantages of participation are that the patients have to make additional visits to the clinic and that visits may take longer. During the follow-up visits, the ophthalmologist will use an eye drop to dilate the pupil (to enlarge it). This medication may cause some temporary discomfort (blurred vision).

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

Subjects are eligible for the study if they meet the following criteria:
Note: Ocular criteria must be met in both eyes.
* are willing and able to understand and sign an informed consent;
* * 1.00 Dioptres of corneal astigmatism in both eyes
* are willing and able to attend postoperative examinations per protocol schedule;
* are at least 21 years of age, of either gender and any race;
* require cataract extraction followed by posterior IOL implantation used as an on-label procedure;
* be willing to have second eye surgery within one month of first eye surgery; Note: The second eye surgery should not be performed less than one week (7 days) after the first eye surgery.
* are in good ocular health, with the exception of cataracts;
* are free of disease(s)/condition(s) listed in the *Caution* section of the AcrySof® ReSTOR® +3 and LENTIS® Mplus package inserts

Exclusion criteria

* Planned multiple procedures, including LRI, during cataract/IOL implantation surgery
* Amblyopia
* Previous corneal surgery
* Clinically significant corneal endothelial dystrophy (e.g., Fuchs* dystrophy)
* History of corneal disease (e.g., herpes simplex, herpes zoster keratitis, etc.)
* Diabetic retinopathy
* Macular degeneration
* Subjects with pupil abnormalities (e.g., corectopia)
* History of retinal detachment
* Subjects that have an acute or chronic disease or illness that would increase the operative

risk or confound the results of this investigation (e.g., immunocompromised, connective tissue disease, clinically significant atopic disease, diabetes, and any other such disease or illness)
* suturing of incision required at time of surgery

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):	15-09-2011
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	ReSTOR® Aspheric lens/ LENTIS® Mplus IOL
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-12-2010
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	NL34631.096.10