CLINICAL OUTCOMES AFTER IMPLANTATION OF THE ACRYSOF® IQ RESTOR® +2.5 D MULTIFOCAL INTRAOCULAR LENS (MIOL) IN THE DOMINANT EYE AND RANDOMIZATION OF THE ACRYSOF® IQ RESTOR® +2.5 D OR +3.0 D MIOL IN THE FELLOW EYE

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The primary objective is to demonstrate non-inferiority of patients bilaterally implanted with the AcrySof® IQ ReSTOR® +2.5 D MIOL to AcrySof® IQ ReSTOR® +2.5 D MIOL in the dominant eye and AcrySof® IQ ReSTOR® +3.0 D in the fellow eye in binocular...

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

Summary

ID

NL-OMON37230

Source
ToetsingOnline

Brief title
ACRYSOF® IQ RESTOR® +2.5 D MIOL versus ACRYSOF® IQ RESTOR® +3.0 D MIOL

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 Research Ltd.

Intervention

Keyword: cataract visus, comparison, implant, multifocal intraocular lens

Outcome measures

Primary outcome

Binocular distance corrected visual acuity at 60 cm at Visit 3A (90 ± 14 days).

Secondary outcome

Binocular distance corrected visual acuity at 40 cm at Visit 3A (90 ± 14 days).

Study description

Background summary

The standard treatment for a cataract is surgical removal of the natural lens. This is usually replaced by a *monofocal* IOL. This is comparable to a contact lens being implanted inside the eye. With *monofocal* IOLs, one can only see clearly at a distance. Therefore the patient will also need glasses to see well at a short or middle distance.

Multifocal Intraocular lenses have been available for more than 20 years. They make it possible to see both at a distance and close up or in the middle distance at the same time.

Study objective

The primary objective is to demonstrate non-inferiority of patients bilaterally implanted with the AcrySof® IQ ReSTOR® +2.5 D MIOL to AcrySof® IQ ReSTOR® +2.5 D MIOL in the dominant eye and AcrySof® IQ ReSTOR® +3.0 D in the fellow eye in binocular distance corrected visual acuity at 60 cm at Visit 3A (90 ± 14 days).

The secondary objective is to demonstrate non-inferiority of patients

bilaterally implanted with the AcrySof® IQ ReSTOR® +2.5 D MIOL to AcrySof® IQ ReSTOR® +2.5 D MIOL in the dominant eye and AcrySof® IQ ReSTOR® +3.0 D in the fellow eye in binocular distance corrected visual acuity at 40 cm at Visit 3A (90 ± 14 days).

Study design

This is a prospective, randomized, patient-masked study requiring implantation of the AcrySof® IQ ReSTOR® +2.5 D MIOL in the dominant eye and randomization to either the AcrySof® IQ ReSTOR® +2.5 D MIOL or AcrySof® IQ ReSTOR® +3.0 D MIOL in the fellow eye of approximately 100 patients (200 eyes). Post IOL implantation, patients will be assessed at 1-day, 1-month, and 3-month intervals.
For each patient the study will normally take about 7 months.

Both lenses included in this study are approved products and will be used according to their directions for use.

The purpose of this study design is to compare clinical outcomes, specifically binocular distance corrected visual acuity at 60 and 40 cm, of patients bilaterally implanted with the AcrySof® IQ ReSTOR® +2.5 D MIOL to patients implanted with AcrySof® IQ ReSTOR® +2.5 D MIOL in the dominant eye and AcrySof® IQ ReSTOR® +3.0 D in their fellow eye. The hypothesis is that the visual outcomes will be similar between the two groups. Supporting endpoints include contrast sensitivity, patient reported outcomes, reading speed, and defocus testing. A descriptive comparison of these endpoints will also be made between the two arms to show the differences, if any, that a patient may have with these lens models. This information will allow the surgeon and patient to make an informed decision about their treatment options after cataract extraction.

Intervention

Eye surgery with removal of the original lens and replacement by an intraocular lens.

Study burden and risks

The patients will be asked to visit the hospital 7 times in 7 months. Each visit will take in between 20 minutes and 3 hours. Exceptionally a visit can take longer. None of the tests are experimental.

There some risks associated with routine cataract surgery. These risks include bleeding, infection, inflammation, detachment of the retina, increased eye pressure, and swelling under the retina. There is a small chance that vision could actually be made worse by the surgical procedure. If the lens is not in the correct position, the vision may also be affected and the normal flow of

fluid within the eye may be blocked. The patient may require additional surgery to treat these side effects and improve surgery results.

In addition to the risks associated with routine cataract surgery, the patient may be more likely to experience visual symptoms such as glare, haziness, halos around lights, double vision, colour distortions, straight lines or flat surfaces that appear curved, distorted vision, blurred vision, and queasiness to thestomach related to the visual symptoms when implanted with the AcrySof® IQ ReSTOR® +2.5 D or +3.0 D Multifocal IOL.

Multifocal lenses are significantly different than standard monofocal lenses. Although the multifocal lens is designed to provide near and intermediate vision in addition to distance vision, it is possible that the patient's near vision may not be as clear or as sharp in low light as with a monofocal lens implant when used with glasses. Even with a multifocal lens, the patient may also need to wear reading glasses to see up close under dim lighting conditions.

The potential vision problems listed above may trouble the patient enough to require removal of the intraocular lens that was implanted. If there is a reduction in the vision (near or far) or if the patient has visual symptoms that cannot be tolerated, the doctor may need to perform a second surgery to reposition, remove or replace the intraocular lens.

During the study, at different visits, the patient may have eye drops used for pupil dilation which may cause temporary sensitivity to light and blurred vision. Sunglasses should be worn in bright light. Driving a car or performing any hazardous activity should not be done until the effects of the medication are gone and normal vision returns.

Eye pressure may be tested during the study. The eye pressure test involves the placement of eye drops containing a small amount of a numbing drop into the eye. It is important that the patient does not rub your eyes for at least fifteen (15) minutes after the drops are put in the eye, since small particles or dust in the eye might scratch the cornea and the numbing drop would make the patient temporarily unable to feel the pain. Minor scratching of the corneal surface may rarely occur when the pressure in the eye is measured.

In addition, there is always the risk that uncommon or previously unknown side effects may occur.

Effects of the implantation of an intraocular lens to an unborn baby or breast-feeding infant are unknown; however intraocular lenses are commonly used during pregnancy.

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

1.are adult patients 21 years of age or older at the time of surgery, of either gender or any race;
2.are willing and able to understand and sign an informed consent;
3.are willing and able to attend postoperative examinations per protocol schedule;
4.require cataract extraction followed by posterior IOL implantation used as an on-label procedure in both eyes;
5.be willing to have second eye surgery within 45 days of first eye surgery;
6.are free of severe disease(s)/condition(s) listed in the *Warnings* and *Precautions* section of the AcrySof® IQ ReSTOR® +2.5 D and AcrySof® IQ ReSTOR® +3.0 D MIOL package inserts;
7.are expected to have postoperative astigmatism < 1.0 D in both eyes, measured by keratometry.

Exclusion criteria

1.Refractive lens exchange (CDVA should be worse than 20/20);
2.Significant irregular corneal astigmatism as demonstrated by corneal topography;
3.Patients diagnosed with severe degenerative visual disorders (e.g. macular degeneration or other retinal disorders);
4.Previous corneal surgery;
5.Amblyopia;
6.Planned multiple procedures, including LRI, LASIK, etc. during surgery or the course of this study;
7.Clinically significant corneal endothelial dystrophy (e.g., Fuchs* dystrophy);
8.History of corneal disease (e.g., herpes simplex, herpes zoster, etc.);
9.Severe diabetic retinopathy;
10.History of retinal detachment;
11.Patients who have severe conditions of acute or chronic diseases or illnesses that, per investigator*s clinical judgment, would increase the operative risk or confound the results of this investigation;
12.Any patient currently participating in another drug or device study;
13.Pregnant or planning pregnancy during course of study.

Study design

Design

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):	26-11-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	ACRYSOF® IQ RESTOR® +2.5/+3.0 D MULTIFOCAL INTRAOCULAR LENS (MIOL)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-10-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-09-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT01684007
CCMO	NL41699.068.12