Clinical Investigation of Visual Function After Bilateral Implantation of Two Presbyopia-Correcting Trifocal IOLs.

Published: 03-06-2016
Last updated: 16-04-2024

Primary Objective:To demonstrate noninferiority of ACRYSOF IQ PanOptix presbyopia-correcting IOL Model TFNT00 to the AT LISA tri IOL Model 839MP in mean photopic binocular uncorrected intermediate (60 cm) visual acuity at Visit 4A.Secondary...

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

Summary

ID

NL-OMON43373

Source
ToetsingOnline

Brief title
Investigation of Two Presbyopia-Correcting Trifocal IOLs.

Condition

- Vision disorders

Synonym
Presbyopia

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories
Source(s) of monetary or material Support: Alcon Research Ltd.

Intervention

Keyword: IOL, PanOptix, Presbyopia

Outcome measures

Primary outcome

A combination of gate-keeping and Bonferroni adjustment strategies will be employed to control the overall type I error rate.

Descriptive statistics generated for safety and performance parameters will be based upon the type of parameter (ie, whether the data are categorical or continuous) being analyzed and by 1st and 2nd operative eyes for monocular measures. For categorical parameters, the statistics used to summarize the data descriptively include sample size, number in the category, and percent in the category. For continuous parameters, sample size, mean, median, standard deviation, minimum, and maximum will be presented.

Summaries of logMAR visual acuity will also include two-sided 90% confidence intervals. A composite visual acuity endpoint comprising binocular uncorrected visual acuity at Distance (4 m) and Near (40 cm) will be summarized as a categorical variable with the following categories 20/20 or better (* 0.04 logMAR), 20/32 or better (* 0.14 logMAR) and 20/40 or better (* 0.24 logMAR).

Responses to the satisfaction question will be analyzed as a categorical variable. Contrast sensitivity will be scored and analyzed per CSV-1000E instructions.

Defocus curves will be generated for binocular defocus data, including 90%

confidence intervals, with amount of defocus along the x-axis and logMAR VA at each defocus point along the y-axis. To examine the inter-site variation in outcome, a forest plot will be produced by plotting the difference in means and associated standard error for each site.
An interim analysis will be performed when all subjects complete Visit 3A (20-40 days post 2nd eye implantation) in order to support the study publication plan of the test articles for near, intermediate and distance visual acuity, contrast sensitivity, defocus curves and adverse events.
The interim analysis results will be distributed to a limited audience to limit potential bias in Visit 4A assessments. The clinical trial team with the exception of the Brand Lead will be masked to the interim analysis results.

Secondary outcome

Not applicable.

Study description

Background summary

Presbyopia is a condition in which the eye gradually loses the ability to focus on near objects, or accommodate. This condition affects almost all people aged sixty and beyond. The modern day quest for perfect vision after cataract surgery includes restoration of this accommodative capability. Several approaches for treating presbyopia through the design of IOLs exist in practice, including the use of multifocal IOLs. Multifocal IOLs offer the cataract patient an opportunity to have the effects of presbyopia corrected after cataract surgery by providing multiple focal points. The majority of commercially available multifocal IOLs provide two optical zones for distance and near vision. The ACRYSOF IQ PanOptix Presbyopia IOL Model TFNT00 uses similar technology of commercially available multifocal IOLs to create an additional focal point for intermediate vision.

Study objective

Primary Objective:
To demonstrate noninferiority of ACRYSOF IQ PanOptix presbyopia-correcting IOL Model TFNT00 to the AT LISA tri IOL Model 839MP in mean photopic binocular uncorrected intermediate (60 cm) visual acuity at Visit 4A.

Secondary Objectives:
1. To demonstrate superiority of ACRYSOF IQ PanOptix IOL versus the AT LISA tri IOL Model 839MP in mean photopic binocular uncorrected intermediate (60 cm) visual acuity at Visit 4A.
2. To demonstrate noninferiority of ACRYSOF IQ PanOptix IOL versus the AT LISA tri IOL Model 839MP in mean photopic binocular uncorrected distance (4 m) visual acuity at Visit 4A.
3. To demonstrate noninferiority of ACRYSOF IQ PanOptix IOL versus the AT LISA tri IOL Model 839MP in mean photopic binocular uncorrected near (40 cm) visual acuity at Visit 4A.
4. To demonstrate superiority of ACRYSOF IQ PanOptix IOL versus the AT LISA tri IOL Model 839MP in mean photopic binocular uncorrected near (40 cm) visual acuity at Visit 4A.
5. To demonstrate superiority of ACRYSOF IQ PanOptix IOL versus the AT LISA tri IOL Model 839MP in mean photopic binocular uncorrected distance (4 m) visual acuity at Visit 4A.
6. To characterize the binocular defocus curve profiles, contrast sensitivity and patient satisfaction with ACRYSOF IQ PanOptix IOL versus the AT LISA tri IOL Model 839MP at Visit 4A.

Study design

This study is a prospective, multi-center, randomized, double masked, parallel group postmarket trial.

A total of six hypothesis tests will be conducted to address the primary and secondary objectives of the study. The primary, second secondary and third secondary will be tests of non-inferiority while the first secondary, fourth secondary and fifth secondary will be tests of superiority.

Non-inferiority, with a non-inferiority margin of 0.1 logMAR, will be tested for the mean binocular uncorrected photopic visual acuity at each of the following distances, respectively:
* Intermediate (60 cm) (primary)
* Distance (4 m) (second secondary)
* Near (40 cm) (third secondary)

Superiority will be tested for the mean binocular uncorrected photopic visual acuity at each of the following distances, respectively:
* Intermediate (60 cm) (first secondary)
* Near (40 cm) (fourth secondary)

* Distance (4 m) (fifth secondary)

Hypothesis testing will be conducted in the order presented above for both non-inferiority and superiority.

Intervention

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

Study burden and risks

In a period of about 8 months the patients will be asked to visit the hospital 9 times. Six out of 9 visits will take about 1 hour and 3 out of 9 visits about 3 hours. During the last visit the patient will be requested to complete a Patient Satisfaction Question.

None of the assessments or procedures are experimental. However some of them can cause some inconveniences, such as:
- Routine cataract surgery can cause bleeding, infection, inflammation, detachment of the retina, increased eye pressure, swelling under the retina (in the back of the eye), mild pain or discomfort after the surgery and damage to other delicate structures in the eye. There is a small chance that vision could actually be made worse by the surgical procedure.
- During eye examinations the dilating drops or anesthetic drops may sting when they are first placed into your eyes. Dilation of your pupils may cause some temporary glare and blurring of vision.
- Taking images and photographs of your eyes may cause temporary discomfort from bright lights and holding your eye wide open.

Contacts

Public
Alcon Laboratories

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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. Adults, 22 years of age or older at the time of surgery, of either gender or any race, diagnosed with bilateral cataracts with planned clear cornea cataract removal.
2. Able to comprehend and willing to sign informed consent and complete all required postoperative follow-up procedures.
3. Calculated lens power between 13.0 and 30.0 D.
4. Preoperative BCDVA worse than 0.20 logMAR (ie, 0.22 logMAR or worse) in at least one eye.
5. Potential postoperative BCDVA of 0.20 logMAR or better in both eyes based on Investigator expert medical opinion.
Note: Subjects with any pathology that could reduce visual potential should not be enrolled in this trial.
6. Preoperative regular corneal astigmatism of < 1.00 D, in both eyes.
7. Clear intraocular media other than cataract in both eyes.

Exclusion criteria

Prior operation, ocular criteria must be met in both eyes.
1. Subjects who may reasonably be expected to require an ocular surgical treatment at any time during the study (other than YAG capsulotomy).
2. Previous refractive surgery or planned refractive surgery procedures throughout the entire duration of the subjects* participation in the clinical study (including, but not limited to LASIK, astigmatic keratotomy and limbal relaxing incisions);
3. Clinically significant corneal abnormalities including corneal dystrophy (eg, epithelial, stromal, or endothelial dystrophy), inflammation or edema per the Investigator*s expert medical opinion.
Note: conditions including, but not limited to: keratitis, keratoconjunctivitis, keratouveitis, keratopathy, or keratectasia should be excluded.

4. Amblyopia.
5. Previous corneal transplant.
6. Extremely shallow anterior chamber (* 2.5 mm), not due to swollen cataract.
7. Any recurrent severe anterior or posterior segment inflammation of any etiology, and/or history of any disease producing an intraocular inflammatory reaction.
8. Rubella, congenital, traumatic, or complicated cataracts.
9. Situations where the need for a large capsulotomy can be anticipated (eg, diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.).
10. Iris neovascularization.
11. Glaucoma (uncontrolled or controlled with medication).
12. Subjects with diagnosed degenerative eye disorders.
13. History of or current retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or presence of diabetic retinopathy that the Investigator judges could confound outcomes.
Note: Including but not limited to background diabetic retinopathy, diabetic macular edema or proliferative diabetic retinopathy, macular degeneration.
14. Optic nerve atrophy.
15. Subjects who are expected to require retinal laser treatment.
16. Known color vision deficiencies.
17. Pregnancy or lactation current or planned during the course of the study.
18. Any subject currently participating in another investigational drug or device study that may confound the results of this investigation.;During Surgery.
19. Any other additional procedures during the phacoemulsification and IOL implant due to intraoperative complications that require further intervention (including but not limited to posterior capture rupture, vitreous loss, zonular dehiscence that may make the IOL implant less stable, etc.).
20. Uncontrolled intraocular pressure.
21. Significant anterior chamber bleeding.
22. Excessive iris mobility.
23. Mechanical or surgical manipulation required to enlarge the pupil prior to or at IOL implantation (pupil size must be at least 4.5 mm or larger just prior to implantation).
24. Capsulorhexis tears or any areas of *can-opener* capsulotomy.
25. Unrecognized (pre-existing but discovered during surgery) ocular conditions or complications in which the IOL stability could be compromised, including zonular weakness.
26. Zonular or Capsule rupture.
27. Intended IOL haptic placement other than bag-bag.

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	ACRYSOF IQ PanOptix Presbyopia-Correcting IOL Model TFNT00
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NCT02691741
CCMO	NL57171.018.16