VISUAL OUTCOMES AFTER BILATERAL SURGICAL CATARACT PHACOEMULSIFICATION: ACRYSOF® TORIC IOL IMPLANTATION COMPARED TO MONOFOCAL IOL IMPLANTATION.

Published: 28-07-2010
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The objectives of this study are to assess and compare bilateral uncorrected distance visual acuity and distance spectacle independence post bilateral implantation of AcrySof Toric IOLs and monofocal IOLs.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON35005

Source
ToetsingOnline

Brief title
Alcon M-09-047

Condition

- Vision disorders

Synonym
cataract, corneaal astigmatism

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories (U.K.) Ltd.
Source(s) of monetary or material Support: Medical Devices Industry

Intervention

Keyword: astigmatism, cataract, intraocular lens implantation, visual acuity

Outcome measures

Primary outcome

Uncorrected Distance Visual Acuity

Spectacle Independence

Secondary outcome

Vision-related quality of life

Cost of Postoperative Spectacle Correction

Adverse Events & Rate of surgical re-intervention

Study description

Background summary

Developments in cataract surgery are rapidly evolving, including the continuing development of intraocular lenses (IOLs) to correct for optical aberrations including astigmatism.
The objectives of this study are to assess and compare bilateral uncorrected distance visual acuity and distance spectacle independence post bilateral implantation of AcrySof Toric IOLs and monofocal IOLs. Secondary outcomes will include cost of eyeglass purchased and patient vision-related quality of life.

Study objective

The objectives of this study are to assess and compare bilateral uncorrected distance visual acuity and distance spectacle independence post bilateral implantation of AcrySof Toric IOLs and monofocal IOLs.

Study design

This study is a postmarket, subject and observer masked, comparative trial involving the treatment of astigmatism at the time of cataract surgery and assessment of postoperative resource utilization. Subjects will be assessed 1 day after each operative visit and 1 month, 3 months and 6 months following the 2nd eye surgery. Postoperative clinical evaluations will include manifest refraction, visual acuity, keratometry, tonometry, and a patient reported outcome questionnaire.
At the 6-month visit patients will be asked to provide a copy of the spectacles purchase receipt which should be kept as a source document.

Intervention

There are 2 groups of subjects:
Group 1 will receive AcrySof Toric IOL, group 2 monofocal lens implantation.

Study burden and risks

Risks:
This study can have the following complications associated with IOL implantation during surgery:
Complications such as pain, redness or ocular itching and light sensitivity can occur. There is a very small risk for your visual acuity to decrease because of surgery, for example in case of bleeding, infection (endophtalmitis), inflammation, retinal detachment, raise of intra-ocular pressure (i.e. glaucoma) or corneal opacification. The Intra-ocular lens can also change after the surgery.

Further complications associated with the implantation of intraocular lenses may include but are not limited to the following: corneal endothelial damage, acute cornea decomposition, vitritis, cystoid macular edema, corneal edema, papillary block, cyclitic membrane, iris prolaps, hypopyon, infection, transient of persistent glaucoma and secondary surgical intervention. Secundary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspirations or iridectomy for papillary block, wound leak repair, and retinal detachment repair.

Questionnaires:
Furthermore some questionnaires need to be filled out by the subjects.
3 x vision-related quality of life questionnaires.
An additional questionnaires that will assess e.g. costs of spectacles purchased.

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

Ocular criteria must be met in both eyes:
are >= 21 years of age;
have bilateral, age related, cataracts;
have planned cataract removal via phacoemulsification with implantation of an IOL;
are available to undergo second eye surgery within 6 weeks of the first eye surgery;
are in good ocular health, with the exception of cataracts;
-As indicated in the *Precautions* section of the AcrySof Toric and monofocal package inserts, potential subjects should exhibit a favorable preoperative benefit/risk ratio for lens implantation, in the surgeons medical judgment, when one or more of the following conditions exists: choroidal hemorrhage, chronic severe uveitis, concomitant severe eye disease, extremely shallow anterior chamber, medically uncontrolled glaucoma, microphthalmos, non-age-related cataract, proliferative diabetic retinopathy (severe), severe corneal dystrophy, severe optic nerve atrophy, irregular corneal astigmatism, color vision deficiencies, corneal endothelial disease, abnormal cornea, macular or retinal degeneration or chronic drug miosis,

qualify for bilateral AcrySof Toric IOLs on the AcrySof Toric Calculator;
have regular corneal astigmatism;
are able to obtain pupil dilation >= 5.0 mm.

Exclusion criteria

If any of the following exclusion criteria are applicable to either eye, the subject should not be enrolled in the study:
previous corneal surgery and/or reshaping;
abnormality, disease and/or conditions of the cornea (i.e. keratoconus, corneal dystrophy, keratitis, corneal scar, etc.), which would clinically contra-indicate the implantation of a toric intraocular lens;
planned multiple procedures during cataract/IOL implantation surgery;
planned limbal relaxing incision (LRI), Excimer laser treatment or similar procedure prior to or during the course of the study;;pregnant, lactating or planning pregnancy during course of study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	15-05-2010
Enrollment:	146
Type:	Anticipated

Medical products/devices used

Generic name:	Intraoculair lenses

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-07-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-08-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-10-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-12-2010
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
CCMO	NL31888.068.10