Comparison of monocular implantation of the Acrysof Toric T2 intraocular lens with a standard monofocal intraocular lens in subjects with cataracts and low corneal astigmatism

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- Analyse the effect of the toric T2 intraocular lens on quality of vision, compared to a standard monofocal intraocular lens. - Analyse the satisfaction of patients with their visual acuity with the toric T2 intraocular lens, compared to a standard...

Ethical review	Not approved
Status	Will not start
Health condition type	Anterior eye structural change, deposit and degeneration
Study type	Interventional

Summary

ID

NL-OMON35670

Source
ToetsingOnline

Brief title
Comparison Acrysof Toric T2 IOL with standard monofocal IOL

Condition

- Anterior eye structural change, deposit and degeneration

Synonym
cataract

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: de producten worden gratis door het bedrijf ter beschikking gesteld. Verder zijn er aan het onderzoek geen kosten verbonden;omdat het onderzoek wordt uitgevoerd door een co-assistent in haar M3-stage.

Intervention

Keyword: cataract, corneal astigmatism, Toric IOL

Outcome measures

Primary outcome

Uncorrected distance visual acuity (UCDVA); pre- en postoperative for each eye

Secondary outcome

Best corrected visual acuity (BCDVA): pre- and postoperative for each eye

Patient satisfaction with visual acuity for each eye questionnaire pre- and

postoperative

Manifest refraction (spherical and cylindrical) pre- and postoperative for each

eye

Axis of cylinder

Study description

Background summary

Cataract surgery and IOL implantation have developed considerably in the past few years.
Significant numbers of patients having cataract surgery have a degree of preexisting corneal astigmatism,
Toric intraocular lenses are capable of correcting this astigmatism; they

consist of a spherical and toric component. Toric intraocular lenses are available in various cylindrical powers: T3 - T9.
At the moment there is considerable interest in correcting lower degrees of astigmatism; a factor to take into account is surgically induced astigmastim (SIA). The CE-marked Acrysof Toric SN6AT2 with a cilindrical power of 1.00 diopters (0.68 diopters in corneal plane) has not been used yet; it is available for this study.
We want to analyse if correction of this low a magnitude of astigmatism can be accomplished by this toric IOL, and if such correction is clinically meaningful

Study objective

- Analyse the effect of the toric T2 intraocular lens on quality of vision, compared to a standard monofocal intraocular lens.
- Analyse the satisfaction of patients with their visual acuity with the toric T2 intraocular lens, compared to a standard monofocal intraocular lens.

Study design

Prospective, double-blind, randomised, within-patient control pilotstudy.

Intervention

All patients will undergo bilateral cataractsurgery; all surgery will be performed in the standard way by the same experienced surgeon.
Patients will be their own control. In one eye the standard monofocal IOL will be implanted; model model Acrysof SNWF. In the other eye the toric T2 IOL will be implanted; model Acrysof Toric SN6AT2. The lenses have the same design, except for the minimal cylindrical correction on the posterior surface of the toric T2 IOL. The side of implantation of the toric T2 IOL will be determined by randomisation. The surgical technique of implanting both lenses is identical.

Study burden and risks

Patients will undergo the standard preoperative measurements, operative preparations and postoperative measurements. For this study they will have to answer a short questionnaire pre - and postoperative. They will also visit the department of ophthalmology 8 weeks postoperative; UCDVA, BCDVA and manifest refraction will be measured.
Risks of completing the questionnaire and the postoperative measurements are minimal. Risks or adverse events of cataract surgery in this study are not different from cataract surgery carried out outside this study. Possible adverse events of the toric T2 intraocular lens do not differ from a standard monofocal intraocular lens. An advantage for patients in this study is to accomplish refinement of visual acuity. A disadvantage can be the extra time

investment.

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

Bilateral age-related cataracts necessitating surger
Preoperatieve regular corneal astigmatism of > 0,5 D and <1,0 D
Maximum difference in Best Corrected Visual Acuity (BCVA) between both eyes 0,35 Snellen visus

Exclusion criteria

Known ocular pathology which can affect the visus: corneal diseases, glaucoma, macula degeneration, (proliferative diabetic) retinopathy and neuro-opthalmic diseases. Previous corneal or intraocular surgery. History of macular edema, uveitis/iritis, retinal detachment or intraocular inflammation. Irregular astigmatism, pupil abnormalities, tear film abnormalities, iris abnormalities, extremely shallow anterior chamber, optic atrophy, microphthalmos, blind or absent follow eye, amblyopia. Pregnancy and lactation.;Pregnancy, lactation

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:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Acrysof Toric SN6AT2
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	16-08-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL37733.075.11