Effectiveness and cost-effectiveness of TORIC intraocular lens implantation in patients with mild astigmatism

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The primary aim is to evaluate the effectiveness of bilateral toric IOL implantation versus bilateral monofocal IOL in patients that undergo cataract surgery and have a predicted residual refractive astigmatism >=0.75 and

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

Summary

ID

NL-OMON54905

Source
ToetsingOnline

Brief title
the ESCRS TORIC study

Condition

- Vision disorders

Synonym
Astigmatism and cataract surgery, cataract

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: European Society of Cataract and Refractive Surgeons (ESCRS)

Intervention

Keyword: Astigmatism, Cataract, Toric IOL

Outcome measures

Primary outcome

The primary study parameter is the mean UDVA of the toric IOL group after cataract operations compared to the non-toric IOL group.

Secondary outcome

Secondary study parameters/endpoints are:

- Cost-effectiveness: multi-country short-term trial-based economic evaluation (TBEE) and long-term model-based economic evaluation (MBEE);

- The proportion of eyes that achieve postoperative refractive astigmatism <= 0.50 D

- Spectacle independence for distance;

- The proportion of eyes that achieve UDVA >=20/25 and 20/30;

- Prediction accuracy of mathematical models (that estimate the TCA) vs direct measurements of the TCA in mild PEA;

- Change in PROMs from preoperative to 12 weeks postoperative;

- The achieved level of reduced activity limitations after surgery;

- Patient satisfaction with vision.

Study description

Background summary

Annually, 180.000 cataract surgeries are performed in the Netherlands. One in two patients undergoing this operation, have mild astigmatism (>=0.75 en

<=1.50D). Uncorrected astigmatism can cause decreased vision, reading problems, and problems with night-time driving. Implantation of a toric intraocular lens (IOL) can decrease the astigmatism after the operation. In patients with moderate and severe astigmatism (>=1.50 dioptre (D)), there is high-level evidence that toric IOL provide better uncorrected distance visual acuity (UDVA), greater spectacle independence, and lower amounts of residual astigmatism than non-toric IOLs. However, there are no complete and undisputed results in the literature on the efficacy of toric IOLs in patients with mild, clinically relevant astigmatism (>=0.75D and <=1.50D), affecting the majority of cataract patients. We hypothesize that in patients with bilateral cataract and mild regular total corneal astigmatism in the range >=0.75D to <=1.50D, toric lenses result in better-uncorrected intended visual acuity compared to standard lenses.

Study objective

The primary aim is to evaluate the effectiveness of bilateral toric IOL implantation versus bilateral monofocal IOL in patients that undergo cataract surgery and have a predicted residual refractive astigmatism >=0.75 and <=1.50D.

Study design

The study design is a multinational, single-blinded, clinical randomized controlled trial (RCT) with a duration of 36 months.

Intervention

The intervention group will receive bilateral phacoemulsification with toric IOLs. The control group will receive bilateral phacoemulsification with non-toric monofocal IOLs. Patients and investigators will be blinded to the intervention allocation.

Study burden and risks

All intraocular lenses used in this study have a Conformité Européenne (CE) marking and are commercially available. Standard phacoemulsification techniques will be used to implant both types of IOLs. Most measurements and examinations in this study are part of the regular medical treatment of patients with astigmatism who need cataract surgery. All additional examinations are non-invasive. The study will include one extra visit twelve weeks after the cataract surgery.

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 cataract for which uneventful phacoemulsification and IOL implantation is planned;
- Predicted residual refractive astigmatism of >=0.75 to <=1.50D in both eyes assessed by IOLMaster 700;

Exclusion criteria

- Irregular astigmatism or abnormal corneal topography;
- Previous intraocular or corneal (refractive) surgery;
- Hard contact lens wear;
- Dilated pupillary diameter smaller than 6 mm;

- Projected corrected visual acuity higher than 0.2 logMar (lower than 0.63 decimal);
- Visual limiting ocular comorbidity: e.g. macular pathology, uncontrolled glaucoma;
- Traumatic cataract or pseudoexfoliation;
- Target refraction other than emmetropia;
- Require an IOL that is not within the available power range of the manufacturer;
- Pregnancy (current and planned) or lactation;
- Patients participating in another drug or device investigation;
- Unavailable to undergo second eye surgery within two weeks of first eye surgery;
- Patients unable to consent or complete follow-up visits.

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:	Recruiting
Start date (anticipated):	10-12-2024
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Toric intraocular lens
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-06-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-10-2024
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	NL75080.068.20