# Efficacy and cost-effectiveness of toric intraocular lenses in correcting astigmatism in cataract surgery: A Randomised Clinical Trial

Published: 28-09-2009
Last updated: 04-05-2024

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

## Summary

### ID

NL-OMON36797

**Source**
ToetsingOnline

**Brief title**
Toric IOL Study

### Condition

- Vision disorders
- Eye therapeutic procedures

**Synonym**
astigmatism, cylinder

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Kliniek voor Oogheelkunde
**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** Astigmatism, Cataract, Intraocular lenses, Randomized clinical trial

## Outcome measures

### Primary outcome

The primary endpoint is the quality of vision, measured using a patient questionnaire (the National Eye Institue 42 items Refractive Quality of LIfe, NEI RQL-42)

### Secondary outcome

Secondary endpoints are: visual acuity, frequency of spectacle wear, manifest refraction, higher-order wavefront aberrations, contrast sensitivity, occurrence of complications and costs of postoperative spectacles.

# Study description

### Background summary

A recent innovation in cataract surgery consists of the introduction of toric intraocular lenses (IOLs) that can correct corneal astigmatism. It offers the opportunity for patients with substantial astigmatism to achieve optimal distance vision without using spectacles. Good near vision may subsequently be achieved with low-cost reading glasses. The current practice of non-toric IOL implantation in astigmatic patients warrants the use of expensive bifocal or multifocal spectacles with cylinder correction to achieve good distance and near vision. The toric IOL costs about ¤400 more than a non-toric IOL and it is estimated that implementation of toric IOLs in cataract surgery could lead to a considerable increase in costs of about ¤14.000.000. Before these new toric IOLs can be implemented in the regular health care system their efficacy in improving distance vision and cost-effectiveness have to be proven in a

randomised clinical trial.

### Study objective

The primary objective of this study is to compare the quality of vision following toric IOL implantation and monofocal IOL implantation. The secondary objectives are to compare uncorrected distance vision, spectacle dependence, residual refractive astigmatism, wavefront aberrations, contrast sensitivity, complication profile, costs of postoperative spectacles and cost-effectiveness.

### Study design

Multi-centre randomised controlled clinical trial.

### Intervention

Cataract surgery with implantation of a toric IOL (AcrySof SN6ATT) or a monofocal IOL (AcrySof SN60WF).

### Study burden and risks

Most measurements and examinations in this study are part of the standard of care in cataract surgery. Extra examinations are aberrometry, contrast sensitivity and patient questionnaires. Aberrometry and contrast sensitivity are non invasive, cause no side-effects and each take about 5 minutes to perform. Patients will be asked to fill out questionnaires three times. Five postoperative visits for each patient are included in this study, which is one more compared to standard (sequential) cataract surgery. Patients will be offered a travel compensation for this extra visit. We suspect that patients implanted with a toric IOL might benefit from this study, because of an improved distance vision and reduction in cost of postoperative spectacles.

## Contacts

**Public**
Selecteer

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Selecteer

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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
- Regular corneal astigmatism of minimal 1.25 diopters in both eyes
- Both eyes eligible for a toric intraocular lens implantation

## Exclusion criteria

- Severe age-related macular degeneration
- Glaucoma related extensive visual field loss
- Extensive Diabetic macular disease
- Fuchs endothelial dystrophy

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |

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| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 02-02-2010 |
| Enrollment: | 82 |
| Type: | Actual |

### Medical products/devices used

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

## Ethics review

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| Approved WMO Date: | 28-09-2009 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 09-02-2010 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 29-07-2011 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 11-11-2011 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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 | NCT01075542 |
| CCMO | NL29280.068.09 |