Effect of improved intraocular lenses on contrast sensitivity tests.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23838

Source

Brief title Aspheric IOL and contrast sensitivity

Health condition

Each patient will receive a spherical IOL in one eye and an aspherical IOL in the fellow eye. The spherical IOL is normally used, the aspherical is not. The IOL's are CE approved.

Sponsors and support

Primary sponsor: University Hospital Groningen, department ophtalmology

Hanzeplein 1 Postbus 30.001 9700 RB Groningen The Netherlands Tel: (+31)050-3612510 Fax: (+31)050-3611709

AMO (advanced medical optics) Groningen B.V. Van Swietenlaan 5 9728 NX Groningen Tel: (+31)050-5296600 Fax: (+31)050-5267860 **Source(s) of monetary or material Support:** SenterNovem

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Intervention

Outcome measures

Primary outcome

Improvement of the contrast sensitivity in the aspheric IOL.

Secondary outcome

- 1. No decrease of depth of focus.
- 2. No difference in intraocular stray light.

Study description

Background summary

Refractive surgery is a surgical treatment, which aims for the correction of refractive errors. Nowadays, there is a strong tendency to perform refractive surgery in such a way that spherical aberration and other optical abnormalities after the operation are minimal. In patients with cataract, this can be achieved by replacing the cataracteus lens by a synthetic aspherical IOL (intra-ocular lens). An aspherical IOL contains negative spherical aberration which compensates the positive spherical aberration of the cornea.

Study objective

Implantation of aspheric IOL's results in higher visual performance than spheric IOL's.

Intervention

Two groups of 30 patients, each group tested with a specific intraocular lens (IOL) type in a spheric and aspheric design. In each patient a spherical IOL is placed in one eye and an aspherical IOL in the fellow eye. The IOL's used in the first combination are acrylic based and the IOL's used in the second combination are silicone based. Both combinations of IOL's are CE-approved. After implantation of the IOL in the second eye, the patient will perform two different contrast sensitivity tests at optimal refractive state of the eye and at -2D, -1D, +1D and +2D defocus. In this studie, the spherical aberration, corneal topography and stray light will also be measured.

Contacts

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Eligibility criteria

Inclusion criteria

Cataract in both eyes.

Exclusion criteria

- 1. Other ocular pathology as diabetic, macula degeneration and glaucoma;
- 2. Cylinder larger than 1,5 D;
- 3. Medication that influences the tear function of the eye;
- 4. Pathology that influences the tear production;
- 5. Prevalance of pathology between the two cataract operations;
- 6. Younger than 18 years;
- 7. Prevalance of senile dementia (MMSE<22).

Study design

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Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2006
Enrollment:	60
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	20-11-2006
Application type:	First submission

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
NTR-new	NL800
NTR-old	NTR813

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Register
Other
ISRCTN

ID : 2 ISRCTN17058178

Study results

Summary results

N/A