

Effect of improved intraocular lenses on contrast sensitivity tests

Submission date 01/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/01/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL800, NTR813

Study information

Scientific Title

Effect of improved intraocular lenses on contrast sensitivity tests

Acronym

Aspheric IOL and contrast sensitivity

Study objectives

Implantation of aspheric Intra-Ocular Lenses (IOLs) results in higher visual performance than spheric IOLs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medisch Ethische Toetsingscommissie, University Medical Center Groningen, date of MEC approval: 25 Oct 2006 (reference number: METc2006.166). We asked for a small change in the protocol on 8 Nov 2006. For this change (amendment) we received approval on 29 Nov 2006 (also METc2006.166).

Study design

Randomised controlled parallel armed trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cataract

Interventions

Two groups of 30 patients, each group tested with a specific 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 IOLs used in the first combination are acrylic based and the IOLs used in the second combination are silicone based. Both combinations of IOLs 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 study, the spherical aberration, corneal topography and stray light will also be measured.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Improvement of the contrast sensitivity in the aspheric IOL.

Secondary outcome measures

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

Overall study start date

01/11/2006

Completion date

01/10/2008

Eligibility**Key inclusion criteria**

Cataract in both eyes

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

60 eyes, ie 30 patients

Total final enrolment

30

Key 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 (Mini Mental State Examination [MMSE] less than 22)

Date of first enrolment

01/11/2006

Date of final enrolment

01/10/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Center Groningen (The Netherlands)

Sponsor details

Department of Ophthalmology

P.O. Box 30001

Groningen

Netherlands

9700 RB

Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/azg/nl/english/azg/>

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Government

Funder Name

SenterNovem (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010	06/01/2021	Yes	No