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Effect of improved intraocular lenses on contrast sensitivity tests

Submission date	Recruitment status	[_] Prospectively registered
01/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2021	Eye Diseases	

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
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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