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Axial IntraOcular Lens position and posterior capsule opacification with a microincisional single-piece open-loop hydrophilic IntraOcular Lens: a randomised trial (XCelens Idea versus single-piece Acrysof IntraOcular Lens)

Submission date
12/12/2006

Recruitment status
No longer recruiting

Registration date
29/01/2007

Overall study status
Completed

Last Edited
12/11/2012

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
FINO1001

Study information

Scientific Title

Study objectives
To assess the axial stability and the Posterior Capsule Opacification (PCO) inhibiting efficacy of a 360° sharp edge hydrophilic IntraOcular Lens (IOL) (Idea, XCelens) and compare it to that of a standard hydrophobic acrylic IOL (Acrysof SA60AT, Alcon) both single-piece open-loop in design with sharp optic edges.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Moorfields and Whittington LREC on the 15th November 2006 (ref: 06/Q0504/96).

Study design
Randomised, bilateral, double-masked clinical trial with intra-individual comparison

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cataract; posterior capsular opacification

Interventions
Intraocular lens implant (XCelens Idea or Acrysof)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Posterior Capsule Opacification (PCO), measured with an image analysis system Automated QUantification of After-cataract (AQUA), scale zero to ten, from digital retroillumination photographs of the posterior capsule at two years.

Secondary outcome measures
1. Anterior chamber depth (mm) with ACMaster
2. Decentration (mm)
3. Refraction
4. Rhexis size (mm^2)
5. Slitlamp biomicroscopy (descriptive)

Overall study start date
28/11/2006

Completion date
28/05/2009

Eligibility

Key inclusion criteria
1. Bilateral age-related cataract
2. Age 40 and older
3. Visual Acuity more than 0.05
4. Normal findings in the medical history and physical examination unless the investigator considers an abnormality to be clinically irrelevant
5. Written informed consent to surgery and participation in the study

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
35 (70 eyes)

Key exclusion criteria
Relevant other ophthalmic diseases (such as pseudoexfoliation, glaucoma, retinal degenerations, ocular trauma, etc.)

Date of first enrolment
28/11/2006

Date of final enrolment
28/05/2009

Locations

Countries of recruitment
Austria

England

United Kingdom

Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

Sponsor details
162 City Road
London
England
United Kingdom
EC1V 2PD

Sponsor type
Hospital/treatment centre

Website
http://www.moorfields.nhs.uk/Home

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Industry

Funder Name

XCelens SA (Switzerland)

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	01/11/2011		Yes	No