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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	[_] Prospectively registered [_] Protocol
Registration date 29/01/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 12/11/2012	**Condition category** Eye Diseases	[_] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

Austria

Study participating centre

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

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Industry

Funder Name
XCelens SA (Switzerland)

Results and Publications

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