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Effect of a plate haptic design on intraocular lens rotational-and-axial stability and posterior capsule opacification: a randomised trial (acrismart versus acrilyc intraocular lenses)

Submission date
12/12/2006

Recruitment status
No longer recruiting

Registration date
29/01/2007

Overall study status
Completed

Last Edited
29/06/2016

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

Protocol serial number
FINO1002

Study information

Scientific Title
Effect of a plate haptic design on IntraOcular Lens rotational-and-axial stability and posterior capsule opacification: a randomised trial (Acrismart versus Acrilyc IntraOcular Lenses)

Study objectives
Is the evaluation of the rotational stability (of importance for toric models), the axial stability (of importance regarding postoperative refractive outcome and refractive surprises) and the development of posterior capsular opacification of a modern MicroIncision Cataract Surgery (MICS)-compatible single-piece IntraOcular Lens (IOL) (Acri.Smart 46S) which is CE-marked and commercially available (since 2004) compared to that of an open-loop three-piece model made of the same optic material (AcriLyc 53N). Both IOL models have sharp optic edges.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Moorfields and Whittington LREC on the 15th November 2006 (ref: 06/Q0504/97).

Study design
Randomised, bilateral, double-masked clinical trial with intra-individual comparison at two centres (Moorfields Eye Hospital [MEH] and Vienna)

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Intraocular lens implant (Acrismart or Acrylic lens)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Posterior capsule opacification (%)

Key secondary outcome(s))
1. Orientation (degrees)
2. Anterior Chamber Depth (ACD) (mm)
3. Decentration (mm)
4. Refraction
5. Rhexis size (mm^2)
6. Slitlamp biomicroscopy (descriptive)

Completion date
28/05/2010

Eligibility

Key inclusion criteria
1. Bilateral age-related cataract
2. Age 40 and older
3. Visual Acuity more than 0.05
4. 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, traumatic cataract and other comorbidity that could affect Posterior Capsule Opacification (PCO) rate, axial and rotational stability (e.g. Marfan syndrome)

Date of first enrolment
28/11/2006

Date of final enrolment
28/05/2010

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
Acri.tec AG (Germany)

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:	01/12/2013		Yes	No