

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

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 ☒ Results
Last Edited 29/06/2016	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
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 (mm²)
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