

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)

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| Submission date 12/12/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 29/01/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 29/06/2016 | Condition category Eye Diseases | <input type="checkbox"/> 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

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

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 (Acrismart or Acrylic lens)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Posterior capsule opacification (%)

Secondary outcome measures

1. Orientation (degrees)
2. Anterior Chamber Depth (ACD) (mm)
3. Decentration (mm)
4. Refraction
5. Rhexis size (mm²)
6. Slitlamp biomicroscopy (descriptive)

Overall study start date

28/11/2006

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

Age group

Adult

Sex

Not Specified

Target number of participants

25 patients (50 eyes)

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

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

Acri.tec AG (Germany)

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: | 01/12/2013 | | Yes | No |