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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/01/2007	**Overall study status** Completed	
Last Edited 29/06/2016	**Condition category** Eye Diseases	

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 (mm^2)
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