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Prospective randomised trial of the surface cytology of 3 different single piece acrylic intraocular lenses (IOL)

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/09/2016	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

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
N0112146488

Study information

Scientific Title
Prospective randomised trial of the surface cytology of 3 different single piece acrylic intraocular lenses (IOL)

Study objectives
The aim of this study is to assess the biocompatibility of the most commonly used IOL Acrysof with two new acrylic IOLs recently approved for use in the UK, Centreflex and Akreso-fit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Surgery: Eye

Interventions
IOL Acrysof vs two new acrylic IOLs recently approved for use in the UK, Centreflex and Akreso-fit

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

Understanding the biocompatibility of these IOLs will enable surgeons to ascertain whether these IOLs are safe for use in all cases, and also whether there are any unexpected complications that may arise on extended analysis such as this.

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/10/2002

Completion date
01/02/2006

Eligibility

Key inclusion criteria
Patients who are undergoing routine cataract surgery without pre-existing ocular of systemic disease.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Pre-existing ocular or systematic disease which may interfere with their post-operative inflammatory course, including diabetic retinopathy, glaucoma, uveitis, pseudoexfloiation, previous eye surgery, contralateral surgery in the previous 4 months, extremes of age (<60, >90 years), significant macular degeneration or amblyopia precluding a post-operative vision of >6 /12, mature cataracts requiring Visual Blue for extraction.

Date of first enrolment
31/10/2002

Date of final enrolment
01/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Roy Harfitt Eye Unit
Sutton, Surrey
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Sponsor information

Organisation
Department of Health

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Richmond House
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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK) NHS R&D Support Funding

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