

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/09/2016	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Paul G Ursell

Contact details
The Roy Harfitt Eye Unit
Sutton Hospital
Cotswold Road
Sutton, Surrey
United Kingdom
SM2 5LT

Additional identifiers

Protocol serial number
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

Intentional

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/02/2006

Eligibility**Key inclusion criteria**

Patients who are undergoing routine cataract surgery without pre-existing ocular or systemic disease.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Pre-existing ocular or systematic disease which may interfere with their post-operative inflammatory course, including diabetic retinopathy, glaucoma, uveitis, pseudoexfoliation, 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

United Kingdom

England

Study participating centre

The Roy Harfitt Eye Unit

Sutton, Surrey

United Kingdom

SM2 5LT

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration