

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/09/2016	<b>Condition category</b> 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**  
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**Contact details**  
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Sutton Hospital  
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United Kingdom  
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## 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**

Interventional

**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