

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

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| <b>Submission date</b><br>30/09/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>30/09/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>09/09/2016       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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 or 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, 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**

England

United Kingdom

**Study participating centre**

**The Roy Harfitt Eye Unit**

Sutton, Surrey

United Kingdom

SM2 5LT

## **Sponsor information**

**Organisation**

Department of Health

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **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