

# Evaluation of reading vision after cataract surgery and lens implantation

<b>Submission date</b> 09/10/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/08/2014	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**

Comparison of near vision performance of the Crystalens® HD against the Technis® Aspheric Intra-Ocular Lens: a randomised controlled trial

**Study objectives**

The Crystalens® HD is a new accommodative intra-ocular lens (IOL) which may potentially improve reading and near vision compared to standard monofocal lenses. The performance of this IOL will be compared to a standard monofocal IOL.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Guys' Hospital Research Ethics Committee, London, 08/10/2009, ref: 09/H804/82

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Cataracts/near vision/intra-ocular lens

**Interventions**

Crystalens® HD vs standard monofocal IOL

Participants and outcome assessors will be blinded to participant allocation.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Visual acuity

All primary and secondary outcomes will be assessed at 1, 3, 6, 12 and 24 months.

### **Secondary outcome measures**

1. Refraction
2. Objective optical image quality
3. Posterior capsule opacification
4. Measurement of IOL position
5. Contrast sensitivity
6. Objective and subjective measure of accommodation
7. Pupil size

All primary and secondary outcomes will be assessed at 1, 3, 6, 12 and 24 months.

### **Overall study start date**

20/11/2009

### **Completion date**

20/11/2011

## **Eligibility**

### **Key inclusion criteria**

1. Both males and females, aged 18 years or older
2. Documented diagnosis of bilateral cataract requiring surgery
3. Potential visual acuity of 6/12 or better in both eyes
4. Patients who require an IOL in the range of 10-30 dioptres
5. Corneal astigmatism less than/equal to 1.0 dioptres after cataract surgery
6. Patients willing and able to provide informed consent and able to attend follow-up appointments

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

80 (40 per group)

### **Key exclusion criteria**

1. Any coexisting ocular disease
2. Treatment with any ocular medication apart from artificial tear drops
3. Patients who are not fluent in English
4. Females of childbearing potential who are currently pregnant or breastfeeding

**Date of first enrolment**

20/11/2009

**Date of final enrolment**

20/11/2011

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**St Thomas' Hospital**

London

United Kingdom

SE1 7EH

## **Sponsor information**

**Organisation**

Guy's and St Thomas' NHS Foundation Trust (UK)

**Sponsor details**

c/o Karen Ignatian

R&D Department

2nd Floor, Conybeare House

Great Maze pond

London

England

United Kingdom

SE1 9RT

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.guysandstthomas.nhs.uk/>

**ROR**

<https://ror.org/00j161312>

# Funder(s)

## Funder type

Government

## Funder Name

Guy's and St Thomas' NHS Foundation Trust (UK) - Cataract and IOL Research Fund

## Funder Name

Fight for Sight (UK)

## Alternative Name(s)

Fight for Sight, Inc., National Council to Combat Blindness, Fight for Sight (U.S.), FFS

## Funding Body Type

Government organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United States of America

## Funder Name

Bausch and Lomb (USA) - providing the lenses

# 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?
<a href="#">Results article</a>	results	01/12/2013		Yes	No

