

Evaluation of reading vision after cataract surgery and lens implantation

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Visual acuity

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

St Thomas' Hospital

London
United Kingdom
SE1 7EH

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust (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

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?
Results article	results	01/12/2013		Yes	No