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Evaluation of reading vision after cataract surgery and lens implantation

Submission date 09/10/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/10/2009	**Overall study status** Completed	
Last Edited 04/08/2014	**Condition category** Eye Diseases	

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
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 seconadry 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 seconadry 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?
Results article	results	01/12/2013		Yes	No