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Acri.LISA® bifocal intraocular lens (Carl Zeiss UK) versus AcrySof® IQ ReSTOR® multifocal intraocular lens

Submission date 16/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/09/2010	**Overall study status** Completed	
Last Edited 02/06/2015	**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

MAUV1007

Study information

Scientific Title
Evaluation of post-operative dysphotopsia and spectacles independence after bilateral multifocal intraocular lens (IOL) implantation for cataract surgery and refractive lens exchange: Acri.LISA® 366D versus AcrySof® SN6AD1 randomised clinical trial

Study objectives
Spectacle independence is a central aim in modern cataract surgery. Although bilateral monofocal intraocular lens (IOL) implantation, aiming for emmetropia (perfect vision) or low myopia (shortsightedness), leads to high levels of patient satisfaction in distance vision, spectacle dependence for reading and other near vision tasks is the usual result. With increasing demands for complete spectacle independence after cataract surgery, multifocal IOLs have been introduced widely in cataract surgery. These have resulted in less spectacle dependence for patients. However, a variable number of patients do complain of problems with glare, haloes and lights especially in the hours of darkness (dysphotopsia symptoms). Dysphotopsia symptoms may vary significantly from patient to patient. The actual incidence of dysphotopsialike symptoms after cataract surgery and multifocal IOL implantation is unknown and most likely quite underestimated.

The Acri.LISA® 366D bifocal intraocular lens (IOL) features a uniform refractive/diffractive optic design to reduce halo and glare side effects associated with multifocal intraocular lens implantation. We aim to examine whether the Acri.LISA® design advantages are reflected in greater freedom from optical side effects such as dysphotopsialike symptoms and similar spectacle freedom after surgery in comparison to one of the current marketleading multifocal IOLs, the AcrySof® SN6AD1.

We propose to conduct a multicentre, prospective randomised controlled trial of 188 patients requiring bilateral cataract surgery. Patients enrolled in the study will be randomised to receive either one of the lenses mentioned above, and their satisfaction with the lens (both subjective and objective) will be assessed at one visit 4 - 6 months post-operatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Patient- and observer-masked prospective 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

Interventions
We plan to randomise patients who have no significant ocular copathology, and are undergoing bilateral sequential cataract surgery or bilateral sequential refractive lens exchanged to either bilateral implantation with an Acri.LISA® multifocal IOL or an AcrySof® IQ ReSTOR® multifocal IOL.

Surgery:
Surgery for lens removal and IOL implantation will take place as per standard procedure and will be undertaken by Consultants only. Surgery for the second eye will take place between 1 to 4 weeks after surgery for the first eye. Post-operative follow-up appointment at Moorfields Eye Hospital four months after second eye operation (both eyes, maximum 1.5 hours duration).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The presence of dysphotopsia symptoms (absent, mild, moderate, severe). Dysphotopsia (glare/haloes/visual disturbances) will be assessed with a questionnaire.

Primary and secondary outcomes to be measured 4 - 6 months post-operatively.

Secondary outcome measures
1. Autorefraction and aberrometry and pupil size measurement using the Tracey aberrometer
2. Manifest subjective refraction and spectacle corrected monocular visual acuity measurement
3. Composite scoring of unaided visual acuity; distance and near monocular photopic. Binocular photopic distance, intermediate (50 - 60 - 70 cm) and near (40 cm) visual acuity. Binocular mesopic intermediate (70 cm), distance and near (using neutral density filters NoirU23). The composite scoring system is to be developed during the trial. Visual acuities will be measured using the New ETDRS logarithmic acuity card (Precision Vision).
4. Maximum binocular reading speed at patient preferred distance (IReST)
5. Binocular Near Reading speed
6. Binocular Contrast sensitivity - Pelli-Robson under photopic/mesopic conditions
7. Forward light scatter (C-quant)
8. Spectacle dependence questionnaire
9. Visual satisfaction questionnaire
10. Quality-of-life questionnaire (QIRC score)

11. Visual disability questionnaire - Catquest-9SF patient outcome questionnaire
12. Intra and postoperative complications
13. Slit lamp findings (dilated pupil): IOL centration
14. Adverse event recording (email and CRF)

Primary and secondary outcomes to be measured 4 - 6 months post-operatively.

Overall study start date
01/09/2010

Completion date
01/09/2012

Eligibility

Key inclusion criteria
1. Patients undergoing sequential bilateral cataract surgery or refractive lens exchange
2. Patients that want to be spectacle independent
3. Male or female, aged 21 years and above

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
188

Key exclusion criteria
1. Any significant ocular co-morbidity (amblyopia, age-related macular degeneration [ARMD], glaucoma, etc) precluding post-operative visual acuity (VA) of 20/30 or better or poor zonular /capsular stability (e.g. after trauma/severe pseudoxanthoma elasticum [PXE])
2. Corneal astigmatism more than 1.50 D on IOLMaster keratometry. Corneal astigmatism between 1.00 - 1.50 D will be reduced using standardised limbal relaxing incisions (LRI).
3. IOLMaster biometry not possible
4. IOL power less than 10D or greater than 30D
5. Professional night drivers, pilots, and other occupations for which induced dysphotopsia may be career threatening
6. Patients with severe psychiatric disorders
7. Vulnerable groups
8. Poor mobility
9. Poor comprehension of written English

Date of first enrolment
01/09/2010

Date of final enrolment
01/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.moorfields.nhs.uk

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Industry

Funder Name
Acri.Tec GMBH (Germany) - A Carl Zeiss Meditec Company

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	01/04/2015		Yes	No