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Evaluation of the "Bag-in-the-Lens" intraocular lens

Submission date 09/11/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/11/2009	**Overall study status** Completed	
Last Edited 18/07/2016	**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
Evaluation of the Morcher BioCom Fold Type 89A "Bag–in–the–Lens" intraocular lens: accommodative performance, near vision and posterior capsule opacification

Study objectives
The aim of this study is to evaluate the accommodative and near visual performance of the BIL in comparison to a conventional in-the-bag IOL.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the St. Thomas' Hospital Research Ethics Committee in February 2008 (Ref: 08 /H0802/12)

Study design
Prospective single-centre unmasked randomised controlled trial with intraindividual comparison.

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
Cataract surgery / intraocular lens / accommodation

Interventions
Phacoemulsification cataract extraction and intraocular lens (IOL) implantation (one of each IOL type randomised to either eye in participants):
1. Investigational IOL: the "Bag-in-the-Lens" IOL (Morcher BioComFold Type 89A)
2. Control IOL: the Alcon AcrySof SA60AT
Follow-up: 2 years

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Objective IOL movement with accommodative effort (µm):
Axial IOL movement measured 3 months postoperatively with partial coherence interferometry (Zeiss AC Master) under three accommodative conditions:
1. physiological near visual stimulation
2. pilocarpine
3. cyclopentolate

Secondary outcome measures
1. Objective amplitude of accommodation (D) measured 3 months postoperatively with aberrometry (Tracey Visual Function Analyzer)
2. Subjective accommodative amplitude (D) measured at 1 and 3 months with the push-up test (RAF rule accommodometer)
3. Defocus curves (logMAR) measured at 1 and 3 months as logMAR visual acuity under defocus conditions between +3D and -3D in 0.5D steps
4. Visual performance (logMAR), measured at 1, 3, 6, 12 and 24 months under the following conditions:
4.1. Distance visual acuity without spectacle correction
4.2. Distance visual acuity with spectacle correction
4.3. Near visual acuity without spectacle correction
4.4. Near visual acuity with distance spectacle correction
4.5. Near visual acuity with near spectacle correction
5. Posterior capsule opacification (percentage area PCO) calculated at 1, 3, 6, 12 and 24 months from digital retroillumination images using POCO software.

Overall study start date
01/02/2008

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Male and female patients aged 18 years and above.
2. Bilateral age related cataracts and otherwise healthy eyes.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

26 patients (52 eyes)

Key exclusion criteria
1. Corneal astigmatism greater than 1.50D (determined by IOL Master keratometry)
2. Pupillary dilation less than 6.0mm
3. Coexisting ocular pathology, including:
3.1. amblyopia
3.2. corneal disease
3.3. inflammatory eye disease
3.4. glaucoma
3.5. diabetic retinopathy
3.6. age related macular degeneration
3.7. previous intraocular surgery

Date of first enrolment
01/02/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Ophthalmology
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's & St. Thomas' NHS Foundation Trust (UK)

Sponsor details
c/o Karen Ignatian
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Hospital/treatment centre

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

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