

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

Submission date 09/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/07/2016	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Research Governance Specialist

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St. Thomas Street

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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