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Study of toric intraocular lens (IOL) versus limbal relaxing incisions in the management of cataract astigmatism

Submission date
12/04/2013

Recruitment status
Stopped

Registration date
15/05/2013

Overall study status
Stopped

Last Edited
18/05/2017

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The quality of vision following cataract surgery is affected by the clarity of the ocular media (transparent substances of the eye, i.e the cornea, intraocular lens [IOL], lens capsule and vitreous gel), focus (corneal curvature and IOL) and co-morbidity, e.g. retinal or optic nerve disease. One aspect of focussing is astigmatism, where the vision is blurred due to the inability of the optics of the eye to focus a point object into a sharp focused image on the retina, and is caused in cataract post-surgical patients by asymmetry of corneal curvature. This study aims to assess the effect of two alternative means of correcting astigmatism to optimise focus. The first is the placement of additional corneal incisions to directly reduce corneal astigmatism and second is the use of toric IOLs which may alternatively be used to compensate for corneal astigmatism.

Who can participate?
Males and females aged over 18 years listed for cataract surgery.

What does the study involve?
The participants are randomly allocated to one of two groups:
Group 1: Corneal Limbal Relaxing Incisions (LRIs). These are paired partial-thickness incisions placed just within the cornea immediately prior to small incision cataract surgery. This technique corrects up to 3D of cylinder, which is the maximum level correctable on the inclusion criteria.
Group 2: IOL. The Tecnis toric IOL is implanted during cataract surgery to correct astigmatism.
The study will be conducted in compliance with the protocol, Good Clinical Practice, and all applicable regulatory requirements.

What are the possible benefits and risks of participating?
The study intervention is a choice between two alternative means of reducing post-operative astigmatism. Additional surgical incisions carry a risk of infection, reduced by the routine use of post-operative antibiotic eyedrops. The corneal incisions may also in the immediate post-operative period give a foreign body sensation in the eye. Toric IOLs may rotate in the eye; if rotation is excessive then surgical repositioning may be required. Both techniques carry the risk

of over- or under-correcting astigmatism, such that spectacle correction of vision remains necessary.

Where is the study run from?
Royal Berkshire NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
May 2013 to January 2014

Who is funding the study?
Abbott Medical Optics Inc. (USA)

Who is the main contact?
Mr Martin Leyland

Contact information

Type(s)
Scientific

Contact name
Mr Martin Leyland

Contact details
Royal Berkshire NHS Foundation Trust
London Road
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United Kingdom
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Additional identifiers

Protocol serial number
13/SC/0050

Study information

Scientific Title
Randomised controlled trial of Tecnis 1-piece toric intraocular lens (IOL) versus limbal relaxing incisions in the management of cataract astigmatism

Study objectives
Toric IOLs may be an effective alternative to limbal relaxing incisions (LRIs) for the treatment of astigmatism post cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire South Central NRES Committee, 05/03/2013, ref: 13/SC/0050

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cataract surgery

Interventions
Reducing astigmatism by comparing toric IOLs vs limbal relaxing incisions (LRIs). This study is a randomised controlled trial of two techniques to control post-operative astigmatism.

Group 1: Corneal Limbal Relaxing Incisions (LRIs). These are paired partial thickness incisions placed just within the cornea immediately prior to small incision cataract surgery. This technique corrects up to 3D of cylinder, which is the maximum level correctable on the inclusion criteria.

Group 2: IOL. The Tecnis toric IOL is can be implanted during cataract surgery to correct astigmatism, and is available in cylindrical powers of 1.00, 1.5, 2.25, 3.00 and 4.00 with a spherical diopter range of 5-34 dioptres. Toric IOL biometry calculations using a proprietary algorithm (AMO Abbott Medical Optical), cross-referenced with standard biometry calculation.

The study will be conducted in compliance with the protocol, Good Clinical Practice, and all applicable regulatory requirements.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Visual acuity
2. Corneal astigmatism

Unaided vision will be measured 2 weeks after the operation
Optician sight test will be carried out 6 weeks after the operation

Key secondary outcome(s))
Visual satisfaction score will be measured 6 weeks after the operation

Completion date
01/01/2014

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Symptomatic cataract
2. Vision 6/12 or worse
3. Corneal astigmatism >0.75D horizontal or >1.25D vertical and (maximum 3.0D)
4. Males and females aged over 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. <18 years of age
2. Astigmatism >3.0D or irregular
3. Dry eye severe enough to affect keratometry despite topical lubricant treatment
4. Ocular co-morbidity

Date of first enrolment
01/05/2013

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Berkshire NHS Foundation Trust
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
Royal Berkshire NHS Foundation Trust (UK)

ROR
https://ror.org/034nvrd87

Funder(s)

Funder type
Industry

Funder Name
Abbott Medical Optics Inc. (USA) will provide the toric IOL at the same price as the non-toric IOL

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?
HRA research summary			28/06/2023	No	No