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Effects of machine-based vs surgeon-based marking in astigmatism-correcting lens implantation during cataract surgery

Submission date
09/07/2018

Recruitment status
No longer recruiting

Registration date
20/07/2018

Overall study status
Completed

Last Edited
08/11/2019

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cataracts are a disease in which the lens of the eye becomes cloudy. This can be caused by age. Astigmatism is a condition where vision may be blurred as a result of an error of the lens. Patients with both cataracts and astigmatism often undergo surgery where an ordinary intraocular lens is inserted. This fixes cataracts, but does not correct astigmatism and therefore patients may still have poor vision.
To correct both astigmatism and cataracts, a type of lens called a toric intraocular lens can be inserted. It is important to insert the toric intraocular lens in the correct axis (the position of the astigmatism) in order to effectively correct the astigmatism.
There are two methods of indicating, or marking, the axis of lens implantation - either using a machine-based method, or manually by the surgeon performing the operation. We aimed to determine which of these methods is more effective.

Who can participate?
Adults with cataracts and corneal astigmatism

What does the study involve?
Participants will undergo lens implantation cataract surgery, and will be randomly allocated to receive this surgery either using a machine or from a surgeon and will receive follow up tests 1 day, 1 month and 2 months after the surgery. Additionally, participants will be tested for uncorrected and best corrected visual acuity before and 1 day, 1 month and 2 months after the surgery.

What are the possible benefits and risks of participating?
The benefit to participants of taking part is that their cataracts will be removed and their astigmatism will be corrected. A possible risk of taking part is complications from cataract surgery, such as infection.

Where is the study run from?
St Mary's Hospital, Seoul, South Korea

When is the study starting and how long is it expected to run for?
February 2014 to April 2018

Who is funding the study?
1. Korean Health Technology R&D Project (South Korea)
2. Ministry for Health & Welfare, Republic of Korea (South Korea)
3. National Research Foundation of Korea (NRF) (South Korea)

Who is the main contact?
Dr Rowoon Yi
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Contact information

Type(s)
Scientific

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Seoul
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Accuracy of Toric Intraocular Lens implantation using Automated Vs Manual Marking

Study objectives
The SensoMotoric Instruments (SMI) is more accurate than manual marking for Toric IOL implantation during cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of Bucheon St. Mary's Hospital, 02/01/2014, HC14RISI0077

Study design
Prospective interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cataracts with corneal astigmatism

Interventions
Participants will be randomised to either SMI group or manual group in a 1:1 allocation using individual-level blocked randomisation stratified by sex (male, female) and age. The randomisation sequence will be computer-generated by the trial statistician and programmed by the data manager.
The SMI group will undergo toric intraocular lens implantation using SMI (SensorMotoric Instruments) marking, whereas the manual group will undergo toric intraocular lens implantation using manual marking (done by a surgeon).
Before and after lens implantation, participants were tested for uncorrected visual acuity, best corrected visual acuity and corneal topography.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Toric intraocular axis, measured using a refractometer 1 day, 1 month and 2 months post-operation

Key secondary outcome(s))
The following are measured by a physician using the logMAR method 1 day, 1 month and 2 months post-operation:
1. Uncorrected visual acuity
2. Best corrected visual acuity

Completion date
01/04/2018

Eligibility

Key inclusion criteria
1. Cataracts
2. Corneal astigmatism > 1.5 diopters
3. Aged over 20

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Total final enrolment
132

Key exclusion criteria
1. Glaucoma
2. Retinal disease
3. Irregular astigmatism

Date of first enrolment
01/02/2014

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Korea, South

Study participating centre
Seoul St. Mary's Hospital
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Sponsor information

Organisation
Ministry for Health & Welfare, Republic of Korea

ROR
https://ror.org/00vxgjw72

Funder(s)

Funder type
Not defined

Funder Name
Ministry for Health & Welfare, Republic of Korea

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rowoon Yi (beneficialyi@gmail.com). The data available will be individual participant data that underlies the results reported after deidentification (text, tables, figures and appendices), along with the study protocol. Data will be available from 9 months after until 36 months after article publication and will be shared with investigators whose proposed use of the data has been approved by an independent review committee. Data provided may be used for individual participant meta-analysis. Proposals should be directed to beneficialyi@gmail.com (Rowoon Yi, clinical fellow) to gain access and data requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/08/2019	08/11/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes