ISRCTN76566080 https://doi.org/10.1186/ISRCTN76566080

Effect of number and position of haptic on anterior capsule contraction

Submission date
06/02/2018

Recruitment status
No longer recruiting

Registration date
14/02/2018

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
In cataract surgery, the lens inside the eye that has become cloudy due to cataracts is removed and replace with an artificial lens. These lens are called intraocular lens (IOL) and they make the vision clear. Sometimes after cataract surgery, people develop a thickening of the back of the lens called opacification. This may lead to complications. For these reasons, preventing opacification is very important and there is many different design of IOLs in worldwide for this purpose. This study aims to investigate the effect of the number and position of IOLs after implantation of three different designs of IOLs.

Who can participate?
Adults aged 55 to 75 years old who have a cataract.

What does the study involve?
Participants are randomly allocated to one of three groups as to which type of intraocular lens (IOL) during cataract surgery. Those in the first group receive the Ophtec Precison. Those in the second group receive the Lucid Korea Microflex. Those in the last group receive the Carl Zeiss Asphina. The same surgeon performs all the cataract surgeries using a standard procedure. At week one, two and six months after the procedure the participants are followed up to assess how their procedures went.

What are the possible benefits and risks of participating?
The three IOLs used in this study are intraocular lenses that have been proven safe and approved by the KFDA in Korea. The products that have already proven the safety of intraocular lenses are unlikely to cause additional risk or benefits to patients.

Where is the study run from?
Seoul St. Mary's Hospital (South Korea)

When is the study starting and how long is it expected to run for?
August 2016 to December 2016

Who is funding the study?
Investigator initiated and funded (South Korea)

Who is the main contact?
Professor Choun-ki Joo (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KC18RESI0081

Study information

Scientific Title
Effect of number and position of intraocular lens haptics on anterior capsule contraction: A randomised, prospective trial

Study objectives
The number and position of IOL haptics might affect anterior capsular contraction. The present study evaluates the capsulorhexis aperture after implantation of three differently designed intraocular lens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Seoul St. Mary’s Hospital Korea, 05/02/2016, ref: KC18RESI0081

Study design
This was a prospective, randomized study of patients who were to undergo cataract surgery at Seoul St. Mary’s Hospital, Seoul, South Korea, between August 2016 and December 2016.

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Patient who have age related cataract in Seoul St.Mary's hospital.

Interventions
Participants who diagnosed senile cataractare included in this study. Nne of the following three randomly assigned IOLs was implanted during each patient’s cataract surgery: Precizon IOL (OPHTEC; IOL A), Microflex IOL (Lucid Korea Inc.; IOL B), and CT Asphina 509M IOL (Carl Zeiss; IOL C). Before the study began, a simple randomization is done with the Excel software (Version 2010, Microsoft). The randomly assigned three type of IOL was implanted during cataract surgery.

The same experienced surgeon (CKJ) performed all cataract surgeries using a standard procedure. Except intraocular lens, the postoperative protocol was same in all groups. At week one, two and six months postoperatively, the area of the anterior capsule opening in these patients was measured using digital retro-illumination images after dilating the pupil, followed by evaluation using the POCOman software.

Intervention Type
Device

Primary outcome measure
Anterior Capsule Opening Size is measured by analyzing the image of digital retro-illumination using POCOman software at 1 week, 2, and 6 months postoperatively.

Secondary outcome measures

Posterior Capsule Opacification is measured also by analyzing the image of digital retro-illumination using POCOman software at 1 week, 2, and 6 months postoperatively.

Overall study start date
01/08/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Aged over 55 years and under 75
2. Presence of age-related cataract
3. Axial length within the normal range (22–25.5 mm)
4. Dilated pupil larger than 8.0 mm in diameter

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Ocular disease
2. Intraocular surgery
3. Laser treatment
4. Glaucoma
5. Severe retinal pathology

Date of first enrolment
02/08/2016

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
Korea, South

Study participating centre

Seoul St. Mary's Hospital
Department of Ophthalmology
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Sponsor information

Organisation
Ethics Committee of the Seoul St. Mary's Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/056cn0e37

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Plans to publish in BMC ophthalmology.

Intention to publish date
01/04/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mihyun Choi, MD at MNyoung23@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/03/2018	29/01/2019	Yes	No