

Comparison of macular thickness and inflammatory cytokine levels after microincision versus small incision coaxial cataract surgery

Submission date 11/12/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/12/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Our goal is to compare the effects of cataract surgery performed using two different sizes of incision (microincision versus small incision).

Who can participate?

Participants who are due to undergo cataract surgery and whose eyes nuclear density ranges from Grade 3 to 4 can take part.

What does the study involve?

Participants will be randomly allocated to one of two groups. One group undergoes cataract surgery with a microincision and the other group undergoes the surgery using a small incision. Clinical measurements are taken before the surgery and one week, one month and two months after the surgery. Participants will be invited to give blood for further blood tests before the surgery and one week after the surgery is completed.

What are the possible benefits and risks of participating?

There is no risk to participants.

Where is the study run from?

The study is run from Bucheon St Mary's Hospital, South Korea.

When is study starting and how long is it expected to run for?

Recruitment started in early 2010. Participants were enrolled in the study for a period of six months; between May 2010 and December 2010.

Who is funding the study?

This study is funded by the National Research Foundation of Korea (NRF).

Who is the main contact?
Professor Eun Chul Kim
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of macular thickness and inflammatory cytokine levels after microincision versus small incision coaxial cataract surgery: a randomized, comparative clinical trial

Study objectives
The pathophysiology of cystoid macular edema (CME) is likely to be multifactorial, but postoperative inflammation and breakdown of the bloodaqueous barrier seem to be important risk factors of onset and subsistence of CME. In this study we compared the macular thickness changes and levels of inflammatory cytokines after microincision versus small incision coaxial cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board at the Bucheon St Mary's Hospital, 07/12/2013, HC13RISI0136

Study design

Randomized comparative clinical trial

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

Interventions

This prospective randomized study included 84 eyes which were randomly allocated to one of the following two treatments:

1. Phacoemulsification with microincision coaxial cataract surgery (2.2 mm incision)
2. Phacoemulsification with small incision

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Intraoperative measurements included:

- 1.1. Ultrasound time (UST)
- 1.2. Mean cumulative dissipated ultrasound energy (CDE)
- 1.3. Total balanced salt solution (BSS) use

2. Clinical measurements included preoperative, 1-week postoperative, 1-month postoperative and 2-month postoperative:

- 2.1. Best corrected visual acuity (BCVA)
- 2.2. Central corneal thickness (CCT)
- 2.3. Endothelial cell count (ECC)

Secondary outcome measures

Enzyme-linked immunosorbent assay (ELISA) and reverse transcription polymerase chain reaction (RT-PCR) were performed for IL-1alpha, IL-6, VEGF and PGE2 preoperatively and at 1 week postoperatively

Overall study start date

01/05/2010

Completion date

01/12/2010

Eligibility

Key inclusion criteria

Eyes with nuclear density from Grade 3 to 4

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

84 patients

Total final enrolment

84

Key exclusion criteria

1. Corneal pathology
2. Pseudoexfoliation
3. History of ocular trauma
4. Intraoperative complications such as posterior lens capsule rupture, lens dislocation and ocular inflammation

Date of first enrolment

01/05/2010

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

Korea, South

Study participating centre

Bucheon St Mary's Hospital
Bucheon
Korea, South
420-717

Sponsor information

Organisation

The National Research Foundation of Korea (NRF) (South Korea)

Sponsor details

201 Gajung-Ro
Yousung- Gu
Daejun
Korea, South
404-829

Sponsor type

Government

Website

<http://www.nrf.re.kr>

ROR

<https://ror.org/013aysd81>

Funder(s)

Funder type

Government

Funder Name

The National Research Foundation of Korea (NRF) (South Korea)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016	17/12/2020	Yes	No