

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

<b>Submission date</b> 11/12/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> 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**  
Prof Eun Chul Kim

**Contact details**  
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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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)

**Key secondary outcome(s)**

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

**Completion date**

01/12/2010

**Eligibility**

**Key inclusion criteria**

Eyes with nuclear density from Grade 3 to 4

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**ROR**

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

**Funder(s)**

**Funder type**  
Government

**Funder Name**  
The National Research Foundation of Korea (NRF) (South Korea)

## 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?
<a href="#">Results article</a>	results	01/05/2016	17/12/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes