ISRCTN69290731 https://doi.org/10.1186/ISRCTN69290731

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

Registration date
03/01/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
eunchol@hanmail.net

Contact information

Type(s)
Scientific

Contact name
Prof Eun Chul Kim

Contact details
Bucheon St Mary's Hospital
2 Sosa-Dong
Wonmi-Ku
Bucheon
Korea, South
420-717

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