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The effect of intracameral anesthesia on macular thickness and ganglion cell-inner plexiform layer thickness after uneventful phacoemulsification surgery

Submission date
01/09/2013

Recruitment status
No longer recruiting

Registration date
20/09/2013

Overall study status
Completed

Last Edited
26/08/2014

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Pseudophakic cystoid macular edema (CME) remains as one of the most common causes of unfavourable visual outcomes after uneventful cataract surgery. Its incidence has been reported as 0.1 to 5% in healthy population. The exact reason is not fully understood. An ideal anaesthetic (numbing) agent for cataract surgery should facilitate this stressful procedure for both the surgeons and the patient. The use of topical anaesthetic agents has gained widespread acceptance, with a preference rate of about 61% among all eye surgeons. Many surgeons who perform cataract surgery under topical anaesthesia also prefer the use of supplementary intracameral lidocaine (used for pupil dilation) during the surgery. Although a conclusion about its safety has not been reached yet, the toxic effects of lidocaine on retinal ganglion cells have been confirmed by previous animal and human studies. In this study we find out the effects of intracameral anaesthesia on specific properties of the macular cells of the eye, after an uneventful cataract surgery in otherwise healthy subjects.

Who can participate?
Patients, aged between 45 and 85 years, requiring cataract surgery for the treatment of senile cataract were enrolled.

What does the study involve?
All patients were randomly assigned to one of two groups : the intracameral lidocaine group received an intracameral injection (into the eye) of lidocaine at the beginning of the procedure, while the sham injection group received an intracameral injection of a dummy. In both groups, two surgeons performed a standard cataract surgery.

What are the possible benefits and risks of participating?
Patients are treated with cataract surgery for the regaining their vision. Some complications can occur such as infection, tear and poor vision after surgery. However, the tests done in this study do not have any potential risks such as radiation exposure.

Where is the study run from?
The study ran from the ophthalmology department of Balikesir University, Turkey.

When is study starting and how long is it expected to run for?
The study ran between March 2013 and June 2013.

Who is funding the study?
The study was funded by the ophthalmology department, Balikesir University, Turkey.

Who is the main contact?
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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
Balikesir University, 2013-16

Study information

Scientific Title
The effect of intracameral anesthesia on macular thickness and ganglion cell-inner plexiform layer thickness after uneventful phacoemulsification surgery: Prospective and randomized controlled trial.

Study objectives

To evaluate the effect of intracameral lidocaine anesthesia on macular thickness and macular ganglion cell-inner plexiform layer (GC-IPL) thickness following uneventful phacoemusification in healthy subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Balikesir University Ethical Committee approved before inclusion of the first cataract patients

Study design
Randomized and double masked study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Senile cataract

Interventions
Optical coherence tomography imaging was performed before and after the cataract surgery
All patients were randomly assigned a number based on a surgical chart:
1. intracameral lidocaine group received an intracameral injection of preservative-free lidocaine 1% (0.5 cc) at the beginning of the procedure
2. sham injection group received intracameral injection of balanced salt solution (BSS) (0.5 cc)
All patients underwent standard phacoemulsification surgery. Optical coherence tomography imaging was performed before surgery and at 1 day, 2 day, 1 week, 1 month and 3 months after surgery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Macular thickness analyses with spectral domain optical coherence tomography measured at baseline and at 1 day, 2 days, 1 week, 1 month and 3 months after surgery.

Secondary outcome measures
Ganglion cell-inner plexiform layer and peripapiller retinal nerve fiber layer thickness analyses as well as visual acuity changes measured at baseline and at 1 day, 2 days, 1 week, 1 month and 3 months after surgery.

Overall study start date
01/03/2013

Completion date
01/06/2013

Eligibility

Key inclusion criteria
Patients requiring phacoemulsification surgery for the treatment of senile cataract were included. Inclusion criteria were the presence of senile cataract between 45 and 85 years of age and a clear fundus examination before the surgery.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100

Key exclusion criteria
Exclusion criteria were
1. Pre-existing macular diseases such as macular edema, epiretinal membrane, macular hole and age-related macular degeneration
2. Ocular diseases such as diabetic retinopathy, glaucoma and previous uveitis
3. Pre-existing refractive error: ±3.00 dioptries
4. History of previous intraocular surgery (except cataract surgery in the fellow eye within the previous 6 months) or laser treatment
5. Diabetes, hypertension or other systemic disease that could affect the eye and topical and/or systemic medications with known interference on macular thickness such as steroids and diuretics.
6. Patients with operative complications and eyes with media opacities which could reduce the signal strength and lead to a segmentation error in preoperative measurements were also excluded from the study.

Date of first enrolment
01/03/2013

Date of final enrolment

01/06/2013

Locations

Countries of recruitment
Türkiye

Study participating centre
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Sponsor information

Organisation
Balikesir University (Turkey)

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Sponsor type
University/education

ROR
https://ror.org/02tv7db43

Funder(s)

Funder type
University/education

Funder Name
Ophthalmology Department, Balikesir University, Turkey

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	01/03/2014		Yes	No