Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

To comparison effect of intracameral adrenalin solution with concentration 1/10000 & 1/100000 on corneal endothelium and macular thickness after uneventful phacoemulsification

Protocol summary

Study aim
Comparison of different concentrations of intraocular adrenaline on corneal endothelium and macular thickness after cataract surgery.

Design
Clinical trial with control group: patients were divided into three groups 1. Patients who received balanced salt solution as placebo. 2. Patients who received epinephrine without preservative with concentration (1:10000). 3. Patients who received epinephrine without preservative with concentration (1:100000). with parallel groups Randomization: two blind groups, the patient and the person who measured the thickness of the macula and the number of endothelium cells and as a person who does not know about the groups. The sample size is 210 patients Phase 3 study

Settings and conduct
This study was conducted in Shiraz Khalili Hospital and Motahari and Poostachi Clinic. The patient and the person who measured the thickness of the macula and the number of endothelium cells were blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: This study is conducted on 210 eyes, patients referred to the dermatology clinic for cataract surgery, all patients are selected in the same age group.Exclusion criteria: patients with a history of eye surgery; eye trauma; Systemic disease such as diabetes mellitus; high eye pressure; exfoliation syndrome; previous endothelium problems; Corneal edema; iris atrophy; macular problems; Complications during surgery (long Phico time, iris trauma, posterior capsule rupture)Complications after surgery

Intervention groups
1. Patients who received balanced salt solution as placebo. 2. Patients who received epinephrine without preservative with concentration (1:10000). 3. Patients who received epinephrine without preservative with concentration (1:100000).

Main outcome variables
Number and characteristics of corneal endothelium cells and macular thickness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141019019581N5**
Registration date: **2023-09-04, 1402/06/13**
Registration timing: **retrospective**

Last update: **2023-09-04, 1402/06/13**
Update count: **0**

Registration date
2023-09-04, 1402/06/13

Registrant information

Name
Shahram Bamdad

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
From shiraz university of medical sciences

Expected recruitment start date
2011-09-23, 1390/07/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To comparison effect of intracameral adrenalin solution with concentration 1/10000 & 1/100000 on corneal endothelium and macular thickness after uneventful phacoemulsification

Public title

To comparison effect of intracameral adrenalin solution with concentration 1/10000 & 1/100000 on corneal endothelium and macular thickness after uneventful phacoemulsification

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

210patients with cataract that refer to poostchi clinic

Exclusion criteria:

Patients with a history of eye surgery Patients with a history of eye trauma Patients with a history of diabetes mellitus and high eye pressure Patients with a history of exfoliation syndrome Patients with a history of corneal edema Patients with a history of macular problems Patients with any complications during the operation, including long phaco time, iris trauma and capsule rupture

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization and assignment were performed using research randomizer software (version 4.0; Urbaniak, G. C. & Plous, S.; 2011), the patients were entered into three groups: intervention 1, intervention 2 and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind technique patient and the person who measured endothelial cell count and macular thickness was blind to grougs

Placebo

Not used

Assignment

Parallel

Other design features

Study design and participants:In this prospective interventional study, we randomly enrolled 210 eligible patients with age-related cataracts, all of whom were scheduled for unilateral phacoemulsification and intraocular lens (IOL) implantation . All the cases underwent a complete ocular examination including Snellen VA, applanation tonometry, slit-lamp exam, and dilated fundus examination. Lens Opacities Classification System (LOCS) III protocol (Chylack et al. 1993) was used preoperatively for grading of nuclear and cortical cataracts to rule out preoperative differences between the two groups . The mean surgery time (min), mean US time, mean US power(%), mean total Us energy, and mean irrigation volume(mL) were measured during the surgery for all patients. Surgical Procedure:Before the surgery, tropicamide 1.0% was used to achieve mydriasis in all patients. All operations were performed by the same surgeon (S. B) and a similar phacoemulsification machine was used for all operations. A similar technique was used for all operations: Using general or local anesthesia, after preparation with Povidone Iodine 10%, a 3.0 mm temporal clear cornea incision was created. Then, the control group did not receive epinephrine; the epinephrine groups received either an injection of 0.2 mL preservative-free epinephrine (1:10000) or 0.2 mL preservative-free epinephrine (1:100000). In all the 3 groups, the same visoelastic (HPMC, Ocucoat, Bausch & Lomb) was injected into the anterior chamber. Then, a continuous curvilinear capsulorhexis was created and Phacoemulsification performed using a stop-and-chop technique. The cortex was aspirated in irrigation/aspiration mode. Sodium hyaluronate 1% (Healon) was injected into the capsular bag and a foldable acrylic IOL implanted in the bag. Viscoelastic was irrigated from the anterior chamber and stromal hydration was used to close the corneal incisions. Topical chloramphenicol and prednisolone acetate eyedrops were given 6 times daily for the first week. Then, Chloramphenicol eye drop was continued 4 times daily for 3 weeks and the prednisolone acetate was slowly tapered during 4 weeks postoperatively and then discontinued. Postoperative examinations included BSCVA, slit-lamp biomicroscopy, IOP measurement, and indirect ophthalmoscopy.Study Outcome Measures:Corneal endothelial density: Central corneal endothelial photographs were taken with the Topcon SP-3000P specular microscope (Topcon Europe BV, Capelle a/d Ijssel,the Netherlands) preoperatively and at 3 month postoperatively. The corneal endothelial morphology was calculated from a central cluster of 10 cells from each photograph. Three photographs were taken from the center and the measurements recorded and veraged. The hexagonality quantifying the percentage of endothelial cells with the ideal hexagonal cell shape was also calculated and recorded. The coefficient of variation in cell size (CV) was also calculated. A comparison between pre- and postoperative values was performed. Macular thickness:

OCT measurements were performed preoperatively and at 1,and 3 months postoperation. Macular thickness measurements were performed using Optical coherence tomography (Spectralis OCT, Heidelberg Engineering, SN:TR-KT-1457, Germany). The central 1.0 mm retinal thickness measurements were taken from the fast macular thickness maps, which were calculated from the 6 low-resolution diagonal scans. The 6 radial diagonal scans were used to quantitatively evaluate the macula. Before the inclusion, all patients in the study had normal macular morphology and thickness.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
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Zand Boulevard
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7134814336
Approval date
2013-10-27, 1392/08/05
Ethics committee reference number
IR.SUMS.REC.1392.2863

Health conditions studied

1

Description of health condition studied
Cataracts
ICD-10 code
H25.1
ICD-10 code description
Age-related nuclear cataract

Primary outcomes

1

Description
Changes in macular thickness in the intervention groups
Timepoint
Before the intervention and three months later
Method of measurement
by specular device

Secondary outcomes

1

Description
Corneal endothelium cell density
Timepoint
Before operation and 3 month after operation
Method of measurement
Specular microscope

2

Description
The size of corneal endothelium cells
Timepoint
Before the operation and 3 months after the operation
Method of measurement
Specular microscope

3

Description
The shape of corneal endothelium cells
Timepoint
Before the operation and 3 months after the operation
Method of measurement
Specular microscope

Intervention groups

1

Description
Patients who received epinephrine without preservative with a concentration of 1.1000
Category
Treatment - Surgery

2

Description
Intervention group: Patients who received epinephrine without preservative with a concentration of 1.100000.
Category
Treatment - Surgery

3

Description
Control group: Patients received balanced salt serum (BSS) as placebo
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalili Hospital
Full name of responsible person
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1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

We have no plans at this time

When the data will become available and for how long

We have no plans at this time

To whom data/document is available

We have no plans at this time

Under which criteria data/document could be used

We have no plans at this time

From where data/document is obtainable

We have no plans at this time

What processes are involved for a request to access data/document

We have no plans at this time

Comments