

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effectiveness of viscoelastic and balance saline solution during intraocular lens injection on increasing of intraocular pressure after phacoemulsification cataract surgery

Protocol summary

Study aim

Cataract surgery without ophthalmic viscoelastic device (OVD) during IOL injection for prevention of intraocular pressure (IOP) increasing and corneal endothelial loss

Design

In this study 70 cataract patient of Khatamolambia hospital are selected and as simple randomize divided 2 groups of 35 people: group 1 ophthalmic viscoelastic device (OVD) and group 2 balance saline solution (BSS) are used during intraocular lens (IOL) injection.

Settings and conduct

IOP are measured by Goldman tonometer in pre surgery, one week after surgery, one month post surgery. The corneal endothelial of patients assess with specular microscopy. This research is double blind

Participants/Inclusion and exclusion criteria

Inclusion criterion: cataract (ns 2-3+). Exclusion criteria: history of eye disease; anti-hypertension drug usage

Intervention groups

Group 1 ophthalmic viscoelastic device (OVD); and group 2 BSS; are used during intraocular lens (IOL) injection.

Main outcome variables

Decrease possibility of high intraocular pressure (IOP) due to ophthalmic viscoelastic device (OVD) use; low cost; decrease of operation time; endothelial loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037577N1**

Registration date: **2018-02-13, 1396/11/24**

Registration timing: **retrospective**

Last update: **2018-02-13, 1396/11/24**

Update count: **0**

Registration date

2018-02-13, 1396/11/24

Registrant information

Name

Abbasali Nozari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3501 8376

Email address

nozariaa931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

2016-05-21, 1395/03/01

Actual recruitment end date

2017-04-19, 1396/01/30

Trial completion date

empty

Scientific title

Comparison of the effectiveness of viscoelastic and balance saline solution during intraocular lens injection on increasing of intraocular pressure after phacoemulsification cataract surgery

Public title

Comparison of the effectiveness of viscoelastic and balance saline solution during intraocular lens injection on increasing of intraocular pressure after

phacomolsification cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cataract nuclear sclerosis (NS)2 or 3 + Decreasing of vision due to cataract

Exclusion criteria:

No ophthalmic disease andophthalmic surgery history No ophthalmic drugs use history No anti-hypertension drugs

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomize method is Simple randomize. Randomization unit is cluster. Cluster of candidate of surgery according to random numbers table are operated with viscoelastic and balance saline solution a month apart. Surgery procedures were recorded in patient file Eexaminer is unaware about surgery procedures was down.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients aware about surgical procedure. Surgery procedures were recorded inpatient file. Examiner don't aware about surgical procedure during preoperation and post operation examination. The encoded data was refereed to statistician for analyzing. Surgeon and examiner are different.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Mashhad Ferdowsi University of Medical Sciences

Street address

Khatamolambia Hospital-Gharani Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2016-04-13, 1395/01/25

Ethics committee reference number

IR.MUMS.FM.REC.1394.621

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H25.1

ICD-10 code description

Age-related incipient cataract

Primary outcomes

1

Description

Intraocular pressure increasing

Timepoint

Intraocular pressure measuring before surgery,1 week and 1 month after surgery

Method of measurement

Goldman tonometer

Secondary outcomes

1

Description

Corneal endothelial cell count

Timepoint

Before surgery and 1 month after surgery

Method of measurement

Speculare microscopy

Intervention groups

1

Description

Intervention group: balance saline solution using during intraocular lens injection

Category

Treatment - Surgery

2

Description

Control group: viscoelastic devise using during intraocular lens injection

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatamolambia hospital

Full name of responsible person

Akbar Derankhshan MD

Street address

Gharani Ave

City

Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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derakhshana@mums.ac.ir

Grant name

Mashhad university research unit

Grant code / Reference number

28194

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Abbasali Nozari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total data of patients and research result are shareable after undetectableng of patients since 2019

When the data will become available and for how long

From 2019

To whom data/document is available

Researchers of academic centers only

Under which criteria data/document could be used

Clinical and practical usage is okay

From where data/document is obtainable

e-mail:abbasalinz@gmail.com tel:00989113720971

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

send a e- mail to abbasalinz@gmail.com

Comments