

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of Central Thickness Changes of Cornea in Linear Phacoemulsification with Torsional Phacoemulsification Surgery in Cataract Patients

Protocol summary

Study aim

Comparison of Central Thickness Changes of Cornea in Linear Phacoemulsification with Torsional Phacoemulsification Surgery 1 day and 1 week after the surgery

Design

Two intervention groups, Parallel Groups, Single Blind, Simply Randomized, 30 patients

Settings and conduct

The patients with cataracts in both eyes who present to the Imamkhomeini hospital of Urmia, will undergo phacoemulsification in both eyes. Based on the statistical estimation, 30 patients will be chosen and the selection of each eye for either linear or torsional surgery is simply randomized and the interval of the two surgeries will be two weeks. The aim to choose both eyes of each patient is to avoid the effects of variables such as age, gender, genetics and systemic diseases affecting the corneal thickness such as diabetes or any other undiagnosed disease, between the two groups. The patients are blind to the method of surgery on each eye.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients over 40 years old, Cataracts in both eyes
Exclusion criteria : Patients under 40 years old, corneal pathologies, poorly dilating pupil or posterior synechiae, pseudoexfoliation, subluxated lens, retinal pathology, glaucoma, diabetes mellitus, collagen vascular diseases, post refractive surgeries

Intervention groups

1) Linear Phacoemulsification Surgery, 2) Torsional Phacoemulsification Surgery

Main outcome variables

Central Corneal Thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231125060168N1**
Registration date: **2023-12-06, 1402/09/15**
Registration timing: **retrospective**

Last update: **2023-12-06, 1402/09/15**

Update count: **0**

Registration date

2023-12-06, 1402/09/15

Registrant information

Name

Reza Soudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

soudi.r@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-26, 1402/08/04

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

2023-10-26, 1402/08/04

Actual recruitment end date

2023-11-25, 1402/09/04

Trial completion date

2023-12-03, 1402/09/12

Scientific title

Comparison of Central Thickness Changes of Cornea in

Linear Phacoemulsification with Torsional
Phacoemulsification Surgery in Cataract Patients

Public title

Comparison of Central Thickness Changes of Cornea in
Linear Phacoemulsification with Torsional
Phacoemulsification

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 40 years old Cataracts in both eyes

Exclusion criteria:

Age under 40 years old corneal pathologies poorly
dilating pupil or posterior synechiae pseudoexfoliation
subluxated lens retinal pathology glaucoma diabetes
mellitus collagen vascular diseases post refractive
surgeries

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

right eye - left eye

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **2**

right eye - left eye

Randomization (investigator's opinion)

Randomized

Randomization description

From the patients with cataracts in both eyes who
present to Imamkhomeini hospital of Urmia, 30 cases will
be chosen based on inclusion or exclusion criteriae. The
method used for randomizing the left or the right eye for
torsional or linear surgery, is the black box. The box will
contain 60 cards and each eye of each patient (left or
right) with the name and family name, will be written on
one card. Each time, one card will be taken out of the
box and each eye of each patient coming out in the first
sequence,will undergo surgery with one of the methods;
and the eye coming out of the box in second sequence,
will undergo surgery with the other type. Determining
the method used for the first sequence is by flapping a
coin.If the first sequence is torsional, the second
sequence will actually be linear or vice versa.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients who present to the hospital to undergo
surgery in both eyes, are blind to the method of surgery
on each eye.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Imamkhomeini Hospital - Urmia
University of Medical Sciences

Street address

Ershad Blvd - Ayatollah Modarres Blvd

City

Urmia

Province

West Azarbaijan

Postal code

8135157157

Approval date

2023-10-25, 1402/08/03

Ethics committee reference number

IR.UMSU.HIMAM.REC.1402.092

Health conditions studied

1

Description of health condition studied

Central Thickness Changes of Cornea

ICD-10 code

H18.23

ICD-10 code description

Secondary corneal edema

Primary outcomes

1

Description

Central Corneal Thickness

Timepoint

Before the surgery, 24 Hours later and 1 week later the
surgery

Method of measurement

Pachymeter

Secondary outcomes

1

Description

Best Corrected Visual Acuity

Timepoint

Before Surgery, 24 Hours later and 1 week later the
surgery

Method of measurement

Snellen Chart

Intervention groups

1

Description

The First Intervention Group : The first group consists of 15 patients who undergo torsional phacoemulsification surgery. The central thickness of cornea in each patient is measured, once 24 hours and once 1 week later, using the pachymeter.

Category

Treatment - Surgery

2

Description

The Second Intervention Group : The second group consists of 15 patients who undergo linear phacoemulsification surgery. The central thickness of cornea in each patient is measured, once 24 hours and once 1 week later, using the pachymeter.

Category

Treatment - Surgery

3

Description

Control group: The control group consists of 30 eyes of 15 patients which will undergo surgery in two parallel torsional and linear groups and the central thickness of cornea of each eye will be measured using the pachymeter.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamkhomeini Hospital

Full name of responsible person

Reza Soudi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

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Urjans Ave, Resalat Blv, Setad Olumpezesghi

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Email

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Reza Soudi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available