

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of topical Dorzolamide on macular thickening after phaco surgery in diabetic patients

Protocol summary

Study aim

Comparison of the effects of dorzolamide eye drops versus placebo (artificial tears) on the prevention of macular thickening following phacoemulsification surgery in diabetic patients

Design

This study is designed as a clinical trial and includes 68 eyes from 68 diabetic patients undergoing phaco surgery.

Settings and conduct

Phacoemulsification surgery in all patients is performed using the same technique. Postoperative examinations are conducted at 1 day, 1 week, 4 weeks, and 12 weeks after surgery, while macular OCT imaging is performed at 1 week, 4 weeks, and 12 weeks postoperatively.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with controlled diabetes who are candidates for phacoemulsification cataract surgery. Exclusion Criteria: Complicated phacoemulsification surgery; history of glaucoma; uveitis; previous ocular surgery; intravitreal drug injection within the past 3 months; history of retinal photocoagulation laser treatment within the past 6 months; presence of proliferative diabetic retinopathy (PDR); macular edema (central macular thickness greater than 320 microns); any prior macular disease and media opacity affecting the quality of OCT macular imaging

Intervention groups

treatment group: 2% dorzolamide eye drops (Dorzamid, Sinadaroo, Tehran, Iran) will be administered since one day prior to surgery and continued for 4 weeks postoperatively, every 8 hours. control group: artificial tears (Tearlose, Sinadaroo, Tehran, Iran) will be given at the same dosage as the treatment group. Additionally, all patients will receive 0.1% betamethasone eye drops every 3 hours during the first week post-surgery, tapered to once daily by the fourth week. Furthermore, 0.3% ciprofloxacin eye drops will be administered every 6 hours for all patients during the first week following the

surgery.

Main outcome variables

Central macular thickness (CMT)

General information

Reason for update

Acronym

PDME

IRCT registration information

IRCT registration number: **IRCT20250111064355N1**

Registration date: **2025-02-06, 1403/11/18**

Registration timing: **registered_while_recruiting**

Last update: **2025-02-06, 1403/11/18**

Update count: **0**

Registration date

2025-02-06, 1403/11/18

Registrant information

Name

Ali Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-15, 1403/10/26

Expected recruitment end date

2025-05-15, 1404/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical Dorzolamide on macular thickening after phaco surgery in diabetic patients

Public title

Effect of Dorzolamide on macular thickness after phaco surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with controlled diabetes (fasting blood sugar [FBS] ≤ 126 mg/dL and hemoglobin A1c [HbA1c] < 7). Patients scheduled for cataract surgery using the phacoemulsification technique.

Exclusion criteria:

Complicated phacoemulsification surgery history of glaucoma uveitis prior ocular surgeries intravitreal drug injection within the past 3 months retinal photocoagulation laser treatment within the past 6 months presence of proliferative diabetic retinopathy (PDR) macular edema (central macular thickness [CMT] > 320 microns) any pre-existing macular disease media opacity interfering with macular OCT imaging

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

The assignment of interventions to patients is conducted randomly using permuted block randomization with random block sizes of 4, 6, and 8 (based on a table of random permutations). The randomization list is prepared by a biostatistician. The intervention used in this study is allocated according to the randomized list by an individual not involved in the study and blinded to its objectives, based on corresponding codes enclosed in sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Evaluation of outcomes was performed by a researcher who was blinded about the group assignment. The study protocol and the type of treatment were concealed from our participants

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Jundishapur University of Medical Sciences, Ahvaz

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Jundishapur University of Medical Sciences, Golestan Highway, Ahvaz, Khuzestan, Iran

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Postal code

6135715794

Approval date

2024-12-07, 1403/09/17

Ethics committee reference number

IR.AJUMS.REC.1403.502

Health conditions studied**1****Description of health condition studied**

Macular Thickening Following Phacoemulsification Surgery in Diabetic Patients

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

central macular thickness (CMT)

Timepoint

Preoperatively, as well as at 1 week, 4 weeks, and 12 weeks postoperatively

Method of measurement

Macular thickness will be measured using SD-OCT (Heidelberg Engineering OCT Spectralis, USA).

Secondary outcomes**1****Description**

visual acuity

Timepoint

Preoperatively, as well as at 1 day, 1 week, 4 weeks, and 12 weeks postoperatively.

Method of measurement

E-chart

2**Description**

intraocular pressure

Timepoint

Preoperatively, as well as at 1 day, 1 week, 4 weeks, and 12 weeks postoperatively.

Method of measurement

Goldmann tonometry

Intervention groups**1****Description**

Control group: Administering Tearlose artificial tear drops (Sinadarou, Tehran, Iran) every 8 hours, from one day before to 4 weeks after Phaco surgery

Category

Placebo

2**Description**

Intervention group: Administering Dorzolamide 2% drops (Dorzamide, Sinadarou, Tehran, Iran) every 8 hours, from one day before to 4 weeks after Phaco surgery

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeyni hospital, Ahvaz

Full name of responsible person

Ali Ansari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Ansari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information available.

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

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