

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 916 792 9956

##### Email address

1375ali.a@gmail.com

##### 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]  $\leq$  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

**Street address**

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

**City**

Ahvaz

**Province**

Khuzestan

**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

#### Street address

Imam Khomeini Hospital, Azadegan Blvd, Ahvaz, Khuzestan, Iran

#### City

Ahvaz

#### Province

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## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Ahvaz University of Medical Sciences

#### Full name of responsible person

Mehrnoosh zakerkish

#### Street address

Jundishapur University of Medical Sciences, Ahvaz, Vice Chancellor for Research and Technology, Ground Floor

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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

Ophthalmology

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Full name of responsible person**

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**City**  
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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