Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Street address
Jundishapur University of Medical Sciences, Golestan Highway, Ahvaz, Khuzestan, Iran
City
Ahvaz
Province
Khouzestan
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
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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
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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 updating data

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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