Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Studying the effect of combination topical therapy using three medications (Dorzolamide drops, Ketorolac drops, Prednisolone drops) in treatment of Ivrin Gass syndrome (CME) post cataract surgery

Protocol summary

Study aim

Determination of changes in macular thickness, determination of changes in patient vision and changes in intraocular pressure (IOP) of the patient in combination therapy with three drops of drazolamide, ketorolac, prednisolone at different times of evaluation

Design

Sample size was calculated using G Power software for 30 samples. In this study, there is no control group and therefore there was no need for blinding. The results are compared with the studies in the American book.

Settings and conduct

All drops are prescribed four times a day. Treatment will continue for up to 2 months after starting treatment. If CME improves before this time, the patient will be examined for up to 8 weeks. The studied variables were patient vision before starting and 2, 4, 8 weeks after starting treatment, IOP before starting and 2, 4, 8 weeks after starting treatment and macular thickness before starting treatment and 2, 4 and 8 weeks after patients will be monitored for side effects from the time of medication and will be excluded from the study in case of any side effects such as drug allergies.

Participants/Inclusion and exclusion criteria

Inclusion criteria: CME patient after uncomplicated cataract surgery, completing the informed consent form to participate. Exclusion criteria: Patients with diabetic retinopathy, retinal and vascular patients and patients with macular disorders are excluded from the study to control confounding variables. Patients with severe renal insufficiency, hepatic insufficiency, etc. are excluded from the study.

Intervention groups

Patients with macular edema after cataract surgery without complications of surgery with derzolamide, ketorolac, prednisolone drops

Main outcome variables

Thickness of the macular center before starting treatment, 2 weeks after starting treatment, 4 weeks after starting treatment, 8 weeks after starting treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051344N1**
Registration date: **2021-09-11, 1400/06/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-11, 1400/06/20**
Update count: **0**

Registration date

2021-09-11, 1400/06/20

Registrant information

Name

Afshin Lotfi sadigh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3657 7330

Email address

lotfisadigh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effect of combination topical therapy using three medications (Dorzolamide drops, Ketorolac drops, Prednisolone drops) in treatment of Ivrin Gass syndrome (CME) post cataract surgery

Public title
Studying the effect of combination topical therapy using three medications (Dorzolamide drops, Ketorolac drops, Prednisolone drops) in treatment of Ivrin Gass syndrome (CME) post cataract surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with CME after uncomplicated cataract surgery completing informed consent form to participate in the study
Exclusion criteria:
Patients with diabetic retinopathy, retinal and vascular patients, patients with macular Patients with severe renal insufficiency, hepatic insufficiency, etc. are excluded from the study.degeneration are excluded from the study to control confounding variables. All patients admitted to the study can withdraw from the study at any time from the start of the study.
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Abbasi street
City
Tabriz
Province
East Azarbaijan
Postal code
۵۱۵۴۶۴۵۳۹۵
Approval date
2021-07-20, 1400/04/29
Ethics committee reference number
IR.TBZMED.REC.1400.356

Health conditions studied

1

Description of health condition studied
Macular edema after uncomplicated cataract surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Macular thickness
Timepoint
Treatment will continue for up to 2 months after starting treatment. If CME improves before this time, the patient will be examined for up to 8 weeks. The studied variables were patient vision before starting and 2, 4, 8 weeks after starting treatment, IOP before starting and 2, 4, 8 weeks after starting treatment and macular thickness before starting treatment and 2, 4 and 8 weeks after From the beginning of treatment
Method of measurement
Oct device and Goldman tonometer

Secondary outcomes

1

Description
intraocular pressure
Timepoint
Treatment will continue for up to 2 months after starting treatment. If CME improves before this time, the patient will be examined for up to 8 weeks. The studied variables were patient vision before starting and 2, 4, 8 weeks after starting treatment, IOP before starting and 2, 4, 8 weeks after starting treatment and macular thickness before starting treatment and 2, 4 and 8 weeks after From the beginning of treatment
Method of measurement
Goldman Tonometer

Intervention groups

1

Description
Intervention group: Among the patients referred to the Charity Eye Medical Center, Tabriz University of Medical Sciences, patients who have uncomplicated cataract surgery and have CME after surgery are included in the study if they wish and with the informed consent of the company. Drozolamide drops, ketorolac drops, prednisolone drops made in Sina Daru factory or other authorized factories, one drop 4 times a day for one month is prescribed. Patient vision, eye pressure, and macular thickness are measured 2, 4, and 8 weeks after treatment.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Nikoukari Eye Hospital

Full name of responsible person
Afshin Lotf Sadigh

Street address
Abbasi

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Tabriz

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East Azarbaijan

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+98 41 3657 7330

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Lotfisadigh@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Mohammad Samiei

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Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
10

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
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Mojtaba Khalili

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Ophthalmology

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Person responsible for updating data

Contact
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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