

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of ketorolac eye drops versus placebo on macular vessel density in cataract patients who underwent phacoemulsification

Protocol summary

Study aim

Determining and comparison of the effect of ketorolac eye drops versus placebo on macular vessel density in cataract patients who underwent phacoemulsification

Design

A controlled clinical trial, two parallel groups design, double-blind, randomized, phase 3 on 76 patients

Settings and conduct

This study will be conducted on adult patients who undergo phacoemulsification in Isfahan Feiz Hospital. After selecting eligible patients and obtaining written informed consent for participation, Patients will be randomly assigned in a 1:1 ratio to one of two intervention and control groups. Before prescribing the drug, each patient's demographic and clinical characteristics will be recorded. After the intervention, both groups will undergo optical coherence tomography (OCT), and the findings related to macular vessel density will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cataract patients who underwent phacoemulsification
Exclusion criteria: Not consenting to participate in the study
Age of fewer than 18 years
History of eye disease affecting the optic nerve and macula
History of intraocular surgery
History of neurological diseases
History of systemic diseases with ocular manifestations

Intervention groups

Patients in the intervention group will receive topical ketorolac eye every six hours for three weeks. Control group patients will be prescribed a placebo eye drop with the same intervals as the intervention group. The routine treatment is a topical corticosteroid, which all patients will receive.

Main outcome variables

Size of foveal avascular zone (mm²)
Vascular density of the parafovea (%)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220216054042N1**

Registration date: **2023-05-08, 1402/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-08, 1402/02/18**

Update count: **0**

Registration date

2023-05-08, 1402/02/18

Registrant information

Name

Atefeh Pirmoradian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3420 7040

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ketorolac eye drops versus placebo on macular vessel density in cataract patients who underwent phacoemulsification

Public title

The effect of non-steroidal anti-inflammatory eye drops vs placebo on macular vessel density following phacoemulsification

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cataract patients who underwent phacoemulsification

Exclusion criteria:

Not consenting to participate in the study
Age of fewer than 18 years
History of eye disease affecting the optic nerve and macula
History of intraocular surgery
History of neurological diseases
History of systemic diseases with ocular manifestations

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Balance Block Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients receive medications in sealed envelopes that are coded. Coding will be done by one of the co-authors, and the prescribing physician, the evaluating physician, and the patient will be blinded

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan Province, Isfahan, Hezar Jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-04-11, 1402/01/22

Ethics committee reference number

IR.MUI.MED.REC.1400.680

Health conditions studied

1

Description of health condition studied

Cataract, Phacoemulsification

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes

1

Description

Size of foveal avascular zone

Timepoint

21 days after initiating the intervention

Method of measurement

Optical coherence tomography

2

Description

Parafoveal vessel density

Timepoint

21 days after initiating the intervention

Method of measurement

Optical coherence tomography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group patients will receive topical ketorolac drops (prescribed for its anti-inflammatory effects, not for pain relief) administered to the eye four times a day for a duration of three weeks. Each patient will likely require three ocular drops during three weeks.

Category

Treatment - Drugs

2

Description

Control group: The control group patients will receive topical artificial tears drops (tearlose) administered to the eye four times a day for a duration of three weeks. Each patient will likely require three ocular drops.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz hospital

Full name of responsible person

Alireza Dehghani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Dehghani

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Atefeh Pirmoradian

Position

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Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Fax**Email**

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