

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation on the Preventive Effects of Ketorolac and Nephaazolin-Anthrazoline Drops on Reducing Patient's Ocular Complications after Phacoamulsification Surgery under sedation

Protocol summary

Study aim

Evaluation of the Preventive Effect of Ketorolac and Nefazolin - Anthrazoline Drop on Reducing Patient's Ocular Complaints after Phacoamulsification Surgery under Sedation

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

This study will be performed on patients with cataract surgery in Isfahan and Feyz Hospital. Patients are divided into two groups. Patients in the first group are treated with ketorolac eye drops, and patients in the second group are treated with nefazolin antazoline eye drops, and the effect of these drops on reducing ocular complaints in patients is investigated. Patients, researchers, and data evaluators will be unaware of the group of patients.

Participants/Inclusion and exclusion criteria

Entry requirements: 1) Patients candidates for cataract surgery under local anesthesia and intravenous sedatives with class one or two American Anesthesia Associations 2) Age between 35 and 88 years 3) Written informed consent to participate in the study No entry conditions: 1) Patients with glaucoma, uncontrolled hypertension, kidney disease, allergies to sedatives or studies 2) Proven mental-anxiety disorders 3) Inability to follow up patients up to 0.5 hours after recovery 4) History of allergy or allergic reaction to sedatives or studies 5) Any sensitivity to ketorolac

Intervention groups

Patients in the first group are treated with ketorolac eye drops, and patients in the second group are treated with nefazolin antazoline eye drops, and the effect of these drops on reducing ocular complaints in patients is investigated.

Main outcome variables

Pain; Nausea; Burning; Itching; Feeling a foreign object in the eye

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046523N1**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

Aryan Rafiee Zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 1582

Email address

rafieezadeh.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-19, 1399/05/29

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation on the Preventive Effects of Ketorolac and Nephaazolin- Anthrazoline Drops on Reducing Patient's Ocular Complications after Phacoamulsification Surgery under sedation

Public title
Preventive Effects of Ketorolac and Nephaazolin- Anthrazoline Drops on Reducing Patient's Ocular Complications

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All of the Patients undergoing Phacoamulsification Surgery under sedation
Exclusion criteria:
Patients with glaucoma, uncontrolled hypertension, kidney disease, allergies to sedatives or studied Proven psycho-anxiety disorders Inability to follow up patients up to 0.5 hours after recovery History of allergy or allergic reaction to Sedatives or studies Any sensitivity to ketorolac

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (for example, top or bottom) and the researcher's second default is to consider even numbers for group 1 and odd numbers for group 2. The researcher begins to read the numbers in a predetermined manner and the patients are divided into two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients will be assigned to two groups. Patients are not relieved of the drug content they receive because the appearance of all medications is the same. Clinical caregivers who give medications to patients also did not know what medication to give. After the course of treatment, to assess the effectiveness of the medication, the assessor does not know which patient has been treated with what medication and only fills in the

information related to the questionnaires.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan
City
Isfahan
Province
Isfahan
Postal code
8174673461

Approval date
2020-06-01, 1399/03/12

Ethics committee reference number
IR.MUI.MED.REC.1399.194

Health conditions studied

1

Description of health condition studied
Cataract

ICD-10 code
H25

ICD-10 code description
Age-related cataract

Primary outcomes

1

Description
Ocular Complaints

Timepoint
Every 15 minutes in the recovery unit and in the ward for half an hour until discharge from the hospital

Method of measurement
Questionnaire

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group1: Receiver of ketorolac. Calm retention will be the same in all patients with midazolam 0.04 kg / mg and fentanyl 1.5 mg / kg. In this group, 2 drops of ketorolac are instilled into the eyes of patients every 6 hours. After 5 minutes, 0.5% tetracycline drops are instilled in both groups, then the eyes are swollen and puffy, and the surgeon will cover the field with phycoamulsification surgery. The patient's operation is transferred to recovery. The patient's eye complaints such as burning, itchy eyes, pain and severity of pain (according to VAS criteria) every 15 minutes in the recovery unit and in the ward every half hour until discharge from the hospital and the patient's satisfaction based on Likert criteria before discharge from the hospital. The study is evaluated and registered by an uninformed witness

Category

Treatment - Drugs

2

Description

Intervention group2: Naphazoline-antazoline drug recipient. Calm retention will be the same in all patients with midazolam 0.04 kg / mg and fentanyl 1.5 mg / kg. In this group, 2 drops of Naphazoline-antazolin are instilled into the eyes of patients every 6 hours. After 5 minutes, 0.5% tetracycline drops are instilled in both groups, then the eyes are swollen and puffy, and the surgeon will cover the field with phycoamulsification surgery. The patient's operation is transferred to recovery. The patient's eye complaints such as burning, itchy eyes, pain and severity of pain (according to VAS criteria) every 15 minutes in the recovery unit and in the ward every half hour until discharge from the hospital and the patient's satisfaction based on Likert criteria before discharge from the hospital. The study is evaluated and registered by an uninformed witness

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz hospital

Full name of responsible person

Hamidreza Shetai

Street address

Feyz hospital, Feyz Ave., Isfahan

City

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

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Email

haghjoo.sh@med.mui.ac.ir

Web page address

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

Hamidreza Shetai

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

From 2021

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Free and on Web Individuals can use the documents by visiting the research sites and the website of Isfahan University of Medical Sciences

From where data/document is obtainable

Free and on Web. Individuals can use the documents by visiting the website of Isfahan University of Medical Sciences and submitting an application

What processes are involved for a request to access data/document

Free and on Web

Comments