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)

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+98 83 3837 1582

Email address

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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 IsfahanUniversity of Medical Sciences

Street address

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

City

Isfahan

Province

Isfehan

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 hospial, Feyz Ave,. Isfahan

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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

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

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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 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