

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of the effect of adding topical ketorolac and tetracaine drops on the need for sedative and analgesic drugs during and after phacoemulsification cataract extraction

#### Protocol summary

##### Study aim

This study aimed to evaluate the effect of using topical ketorolac and tetracaine drops on the need for analgesics in phacoemulsification cataract extraction.

##### Design

This clinical trial is randomized, without any control group, community-based, pragmatic, with parallel groups and double-blinded.

##### Settings and conduct

This study will be carried out at the Feyz Hospital in Isfahan. Before surgery, patients will be hydrated to prevent the possible reduction in blood pressure. A group of patients will receive tetracaine and another group will receive ketorolac, and both groups will be sedated similarly using intravenous fentanyl, midazolam, and propofol. If there is a need for improving sedation, midazolam will be administered, followed by propofol if necessary. If blood pressure is low, ephedrine and atropine will be used after the administration of intravenous fluids. Monitoring will be continued before, during and after the surgery and the degree of sedation, severity of pain and nausea will be assessed according to the visual analogue scale (VAS).

##### Participants/Inclusion and exclusion criteria

All candidates for phacoemulsification cataract extraction undergoing local anesthesia and sedation based on ASA class I and II will be included in this study. The allergy to tetracaine or ketorolac, a history of drug addiction, smoking, alcohol and benzodiazepine abuse, pregnancy, need to change anesthetic technique during surgery or withdrawal from the study is considered as an exclusion criterion.

##### Intervention groups

Tetracaine 0.5% eyedrop will be administered in the first intervention group, and ketorolac 0.5% eyedrop will be administered in the second intervention group. In both groups, every 10 minutes for 30 minutes before the start

of the procedure, one drop will be prescribed.

##### Main outcome variables

Need for midazolam or propofol based on milligrams, the intensity of pain based on VAS scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170716035104N4**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

##### Registration date

2019-06-24, 1398/04/03

##### Registrant information

##### Name

Roham Nik Khah

##### Name of organization / entity

Medical University of Isfahan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 6444

##### Email address

admin.ycc@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

**Actual recruitment start date**

2017-03-21, 1396/01/01

**Actual recruitment end date**

2018-03-20, 1396/12/29

**Trial completion date**

2019-03-20, 1397/12/29

**Scientific title**

Comparison of the effect of adding topical ketorolac and tetracaine drops on the need for sedative and analgesic drugs during and after phacoemulsification cataract extraction

**Public title**

Effect of topical ketorolac and tetracaine on the need for sedative and analgesic drugs in phacoemulsification

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

All candidates of cataract surgery with phacoemulsification under local anesthesia and sedation according to the American Society of Anesthesiologists (ASA) class I and II

**Exclusion criteria:**

Tetracaine allergy Ketorolac allergy History of drug, cigarette, alcohol or benzodiazepine addiction Pregnancy Need for intraoperative alternation of anesthetic technique Opting out of the study

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **86**

Actual sample size reached: **86**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done by the "simple random sampling" method by "Random allocation" software. This software will randomly place the patients in the intervention and control groups based on its randomization algorithm.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants will not be informed about the group they are assigned to (intervention or control). Also, the clinicians and the researchers will not have any information about the patients' groups (intervention or control) and medications used for them.

**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, Hezarjerib Ave., Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2018-01-09, 1396/10/19

**Ethics committee reference number**

IR.MUI.REC.1396.3.741

**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**

Patient's post-operative pain

**Timepoint**

At 0, 10 and 20 minutes after the patient's admission to the recovery

**Method of measurement**

The Visual Analogue Scale (VAS)

**2****Description**

Midazolam doze required for sedation

**Timepoint**

During the surgery

**Method of measurement**

Measured based on milligrams using scaled syringe

### 3

**Description**

Propofol dose required for sedation

**Timepoint**

During the surgery

**Method of measurement**

Measured based on milligrams using scaled syringe

### 4

**Description**

Nausea and vomiting in patient

**Timepoint**

During recovery admission

**Method of measurement**

The Visual Analogue Scale (VAS)

### 5

**Description**

Patient's sedation score during and after the surgery

**Timepoint**

During the surgery and after admitting to the recovery

**Method of measurement**

Visual Analogue Scale (VAS)

## Secondary outcomes

### 1

**Description**

Mean of blood pressure (mm Hg)

**Timepoint**

Prior to the operation, at the 5th, 10th, 15th and 20th minute of the surgery, at the 5th, 10th, 15th and 20th minute after the surgery

**Method of measurement**

Clinical mercury manometer

### 2

**Description**

Heart rate (beats per minute)

**Timepoint**

Prior to the operation, at the 5th, 10th, 15th and 20th minute of the surgery, at the 5th, 10th, 15th and 20th minute after the surgery

**Method of measurement**

Beat count by palpating distal radius pulse

### 3

**Description**

Peripheral capillary oxygen saturation (percentage)

**Timepoint**

Prior to the operation, at the 5th, 10th, 15th and 20th minute of the surgery, at the 5th, 10th, 15th and 20th minute after the surgery

**Method of measurement**

Pulse oximetry

### 4

**Description**

Respiratory rate (breaths per minute)

**Timepoint**

Prior to the operation, at the 5th, 10th, 15th and 20th minute of the surgery, at the 5th, 10th, 15th and 20th minute after the surgery

**Method of measurement**

Capnometry

### 5

**Description**

Hypoxia

**Timepoint**

Prior to the operation, at the 5th, 10th, 15th and 20th minute of the surgery, at the 5th, 10th, 15th and 20th minute after the surgery

**Method of measurement**

Pulse oximetry

### 6

**Description**

Respiratory depression

**Timepoint**

Prior to the operation, at the 5th, 10th, 15th and 20th minute of the surgery, at the 5th, 10th, 15th and 20th minute after the surgery

**Method of measurement**

Capnometry

### 7

**Description**

The satisfaction of the patient and the surgeon according to the Visual Analogue Scale

**Timepoint**

During the admission in the recovery

**Method of measurement**

The Visual Analogue Scale (VAS)

## Intervention groups

### 1

**Description**

Intervention group 1: One drop of tetracaine 0.5% eyedrop will be administered every 10 minutes for 30 minutes before the start of the procedure

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group 2: One drop of ketorolac 0.5% eyedrop will be administered every 10 minutes for 30 minutes before the start of the procedure

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Feiz hospital

**Full name of responsible person**

Dariush Moradi Farsani

**Street address**

Feiz hospital, Modares st.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3445 2034

**Email**

feiz@mui.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh haghjoo javanmard

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Ave.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3668 8138

**Email**

sh\_haghjoo@med.mui.ac.ir

**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**

Hamed Pourkhosravi

**Position**

General physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Ave.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3620 1337

**Email**

hamedpourkhosravi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dariush Moradi Farasni

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Ave.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱۸۱۷۴۶

**Phone**

+98 31 3620 1992

**Email**

dmoradi@med.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamed Pourkhosravi

**Position**

General practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Ave.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱۸۱۷۴۶

**Phone**

+98 31 3620 1337

**Email**

hamedpourkhosravi@gmail.com

**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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available