

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of effect of intracameral marcaine and lidocaine on postoperative pain after cataract surgery in patients undergoing intravenous sedation

#### Protocol summary

##### Study aim

Evaluation of the effect of intracameral marcaine and lidocaine on postoperative pain after cataract surgery in patients undergoing intravenous sedation

##### Design

Two arm parallel group randomized clinical trial, double blinded, randomized

##### Settings and conduct

64 cataract patients will be included in the study and will be randomly divided into two groups. In the first group, local anesthesia and sedation and intracameral lidocaine are used. But in the second group, in addition to local anesthesia and intravenous sedation, marcaine will be injected into the anterior chamber of the eye. Then the pain and hemodynamic parameters of the patients are evaluated.

##### Participants/Inclusion and exclusion criteria

All adult patients with cataracts, regardless of etiology, in the age range of 20-70 years with the class of American Anesthesia Association 1 and 2 who have informed consent enter the study. Exclusion criteria are drug addiction; taking sedatives in last 24 hours; anxiety and other documented psychologic disease and BMI more than 35.

##### Intervention groups

For patients in both groups, to induce local anesthesia, a drop of 0.5% ocular tetracaine is used topically from 20 minutes before the operation and is repeated every 5 minutes until the start of the surgery. In the first intervention group, we inject 0.2 cc of lidocaine 1% without preservative into the anterior chamber immediately after corneal incision and before capsulorexia. In the second intervention group, after receiving topical tetracaine drops as in group 1, immediately after corneal incision and before capsulorexia 0.2 cc of half a percent marcaine without preservative diluted in a 1: 1 ratio with sterile BSS

solution into the anterior chamber.

##### Main outcome variables

Pain; mean arterial pressure; oxygen saturation; patient satisfaction; duration of surgery; average recovery time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210902052364N1**

Registration date: **2021-09-15, 1400/06/24**

Registration timing: **prospective**

Last update: **2021-09-15, 1400/06/24**

Update count: **0**

##### Registration date

2021-09-15, 1400/06/24

##### Registrant information

##### Name

Samira Yavari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5743 4093

##### Email address

samira.yavari1368@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of effect of intracameral marcaine and lidocaine on postoperative pain after cataract surgery in patients undergoing intravenous sedation

**Public title**  
The effect of intracameral marcaine and lidocaine on postoperative pain after cataract surgery in patients undergoing intravenous sedation

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
All adult patients with cataracts, regardless of etiology  
Age range of 20-70 years old  
Class of American Anesthesia Association 1 and 2  
Informed consent to enter the study  
**Exclusion criteria:**  
Drug addiction  
Taking sedatives in last 24 hours  
Anxiety and documented psychologic disease  
BMI more than 35

**Age**  
From **20 years** old to **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, 64 eligible patients will be selected by simple random sampling. These people are then coded with the help of random allocation computer software and are automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly studied in one of the two groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, due to the different nature of the injection (intracameral), the researcher is aware of the two types. However, due to lack of consciousness and the person evaluating the patient's hemodynamic parameters and analyzing the data, the patient will not be aware of the two groups.

**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 street, Azadi square

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8179964167

#### Approval date

2021-05-31, 1400/03/10

#### Ethics committee reference number

IR.MUI.MED.REC.1400.355

## Health conditions studied

### 1

#### Description of health condition studied

Cataract extraction

#### ICD-10 code

Z98.49

#### ICD-10 code description

Cataract extraction status, unspecified eye

## Primary outcomes

### 1

#### Description

Postoperative pain

#### Timepoint

Before anesthesia induction, 15 and 30 minutes after surgery, immediate after entering to the recovery, 15 and 30 minutes after entering the recovery

#### Method of measurement

Visual analogue scale

### 2

#### Description

Mean arterial pressure

#### Timepoint

Before anesthesia induction, 15 and 30 minutes after surgery, immediate after entering to the recovery, 15 and 30 minutes after entering the recovery

#### Method of measurement

Mercury pressure gauge

### 3

#### **Description**

Heart rate

#### **Timepoint**

Before anesthesia induction, 15 and 30 minutes after surgery, immediate after entering to the recovery, 15 and 30 minutes after entering the recovery

#### **Method of measurement**

Heart monitoring

### 4

#### **Description**

Oxygen saturation

#### **Timepoint**

Before anesthesia induction, 15 and 30 minutes after surgery, immediate after entering to the recovery, 15 and 30 minutes after entering the recovery

#### **Method of measurement**

Pulse oxymetr

### 5

#### **Description**

Patient satisfaction

#### **Timepoint**

At the end of recovery time

#### **Method of measurement**

Questionnaire

### 6

#### **Description**

Surgery duration

#### **Timepoint**

At the end of surgery

#### **Method of measurement**

Patient document

### 7

#### **Description**

Recovery time duration

#### **Timepoint**

At the end of recovery

#### **Method of measurement**

Patient document

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: we inject 0.2 cc of lidocaine 1% without preservative into the anterior chamber immediately after corneal incision and before

capsulorexia.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: In the second intervention group, after receiving topical tetracaine drops as in group 1, immediately after corneal incision and before capsulorexia 0.2 cc of half a percent marcaine without preservative diluted in a 1: 1 ratio with sterile BSS solution into the anterior chamber.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Feiz hospital

##### **Full name of responsible person**

Dr Dariush Moradi Farsani

##### **Street address**

Feiz hospital, Ghods square,

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

4487481496

##### **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**

Dr Mojgan Mortazavi

##### **Street address**

Isfahan, hezar jarib street, medical university

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174673461

##### **Phone**

+98 31 3792 8134

##### **Email**

vcr-office@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**

Dr Dariush Moradi Farsani

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Feiz hospital, Ghods square,

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**Province**

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**Postal code**

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**Phone**

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr Dariush Moradi Farsani

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Postal code**

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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**

Dr Samira Yavari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Isfahan, Alzahra hospital, anesthesiology education office

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

Samira.yavari1368@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**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