Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 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)

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+98 31 5743 4093

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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

Isfehan

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,
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4487481496
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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
Dr Dariush Moradi Farsani
Position
Professor
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)
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