Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of intracameral lidocaine on hemodynamic parameters and postoperative pain in cataract surgery under topical anesthesia and sedation

Protocol summary

Study aim

Evaluating the effect of intracameral lidocaine on hemodynamic parameters and postoperative pain in cataract surgery

Design

A randomized single-blinding clinical trial, with the parallel groups

Settings and conduct

In this study, 62 patients candidates for cataract surgery will be included and will be randomly divided into two groups. In the control group, only local anesthesia and sedation are performed. But in the intervention group, in addition to local anesthesia, intracameral lidocaine will be injected. Then the pain and hemodynamic parameters of the patients are evaluated.

Participants/Inclusion and exclusion criteria

Patients in the age group of 40 to 80 years, candidates for cataract surgery using phaco-emulsification, under topical anesthesia and sedation, classified as ASA I and ASA II will be included in the study. Patients with a history of opioids abuse, allergy to lidocaine or tetracaine, history of alcohol and psychotropic substance abuse, history of untreated systemic disease and hemodynamic disorder, history of convulsion, pregnancy/breastfeeding, history of mental illness, taking painkillers 24 hours before surgery and body mass index (BMI) of > 35 kg/m2.

Intervention groups

Control group: For patients in this group to cause local anesthesia, a drop of 0.5% tetracaine ocular drug is used topically from 20 minutes before the operation and is repeated every 5 minutes until the start of surgery. And immediately after corneal incision and before capsulorhexis, four drops of sterile BSS solution are injected into the anterior chamber. Intervention group: For patients in this group, after receiving topical tetracaine drops as in the control group, immediately after corneal incision and before capsulorhexis, four drops of 1% intracameral lidocaine will be injected without preservative.

Main outcome variables

Pain score; heart rate; breath rate; mean arterial blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N16**
Registration date: **2020-12-15, 1399/09/25**
Registration timing: **prospective**

Last update: **2020-12-15, 1399/09/25**
Update count: **0**

Registration date

2020-12-15, 1399/09/25

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intracameral lidocaine on hemodynamic parameters and postoperative pain in cataract surgery under topical anesthesia and sedation

Public title

The effect of intracameral lidocaine on hemodynamic parameters and postoperative pain in cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

An age group of 40 to 80 years old Candidates for cataract surgery using phaco-emulsification Under topical anesthesia and sedation Classified as ASA I and ASA II based on the American Society of Anesthesiologists classification

Exclusion criteria:

History of opioids abuse Allergy to lidocaine or tetracaine History of alcohol and psychedelic abuse History of untreated systemic disease and hemodynamic disorder History of convulsion Pregnancy and breastfeeding History of mental illness Taking painkillers 24 hours before surgery Body Mass Index (BMI) > 35

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 62 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and 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 assigned to one of the two study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, due to the different nature of lidocaine injection in the intervention group (in the eye chamber), the researcher is aware of the treatment used for the two groups. However, the patient due to lack of consciousness and the person evaluating the patient's hemodynamic parameters and the data analyst, will not have any information about the two groups.

Placebo

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

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2020-10-31, 1399/08/10

Ethics committee reference number

IR.MUI.MED.REC.1399.664

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

Mean arterial blood pressure

Timepoint

Immediately before the start of relaxation, 15 and 30 minutes after the start of the operation, at the beginning of recovery, 15 minutes, 30 minutes, 2 hours, 4 hours, 8 hours, 24 hours after surgery

Method of measurement

Monitoring device

2

Description
Heart rate
Timepoint
Immediately before the start of sedation, 15 and 30 minutes after the start of the operation, at the beginning of recovery, 15 minutes, 30 minutes, 2 hours, 4 hours, 8 hours, 24 hours after surgery
Method of measurement
Monitoring device

3

Description
Respiratory rate
Timepoint
Immediately before the start of sedation, 15 and 30 minutes after the start of the operation, at the beginning of recovery, 15 minutes, 30 minutes, 2 hours, 4 hours, 8 hours, 24 hours after surgery
Method of measurement
Monitoring device

4

Description
Pain score
Timepoint
Immediately upon entry to recovery, 15 minutes, 30 minutes, 2 hours, 4 hours, 8 hours and 24 hours after surgery
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: For patients in this group to cause local anesthesia, a drop of 0.5% tetracaine ocular drug is used topically from 20 minutes before the operation and is repeated every 5 minutes until the start of surgery. And immediately after corneal incision and before capsulorhexis, four drops of sterile BSS solution are injected into the anterior chamber.
Category
Treatment - Surgery

2

Description
Intervention group: Intervention group: For patients in the intervention group to cause local anesthesia, a drop of 0.5% tetracaine ocular drug is used topically from 20 minutes before the operation and is repeated every 5 minutes until the start of surgery. Immediately after corneal incision and before capsulorhexis, four drops of 1% lidocaine are injected into the anterior chamber without preservatives.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz Hospital
Full name of responsible person
Daroush Moradi Farsani
Street address
Ayatollah Modarres Street, Quds Square
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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 Javanmard
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Daroush Moradi Farsani
Position
Associate 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 further 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