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)

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+98 31 3668 6444

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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
Isfehan
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 doze 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 admittion
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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Hamed Pourkhosravi
Position
General physician
Latest degree
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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