Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of sedation and analgesia of ketorolac and diclofenac eye drops with tetracaine in cataract surgery

Protocol summary

Study aim
Comparison of sedation and analgesia of ketorolac and diclofenac eye drops with tetracaine in cataract surgery

Design
Parallel group clinical trial with a control group, double blinded, randomized, phase 3 on 99 patients. Sealed envelope software was used for randomization.

Settings and conduct
This study is a randomized and double blinded clinical trial in which patients who are candidates for cataract surgery will be included in the study at Amirkabir Hospital in Arak city.In this study, the patients and the data collector do not know about the grouping of the patients and are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 35 to 85 years old; both sexes;' ASA class 1 and 2; Cataract surgery candidate by Fico method; obtaining informed consent for the intervention; absence of mental disorders; absence of history of chronic use of sedatives; not using alcohol and drugs; not having an allergy to the drugs used. Exclusion criteria: lack of patient permission; the presence of any complications during the operation that lead to changing the anesthesia method used or canceling the surgery.

Intervention groups
The first group: 0.5% tetracaine eye drops along with artificial tear drops, one drop each every 10 minutes during 30 minutes before the operation. The second group: 0.5% tetracaine eye drops along with 0.5% ketorolac drops, one drop each every 10 minutes during 30 minutes before the operation. The third group: 0.5% tetracaine eye drops along with 0.1% diclofenac drops, one drop each every 10 minutes during 30 minutes before the operation.

Main outcome variables
Ramsay scale to evaluate patient sedation and VAS Score to evaluate patient pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130719014056N13**
Registration date: **2023-01-23, 1401/11/03**
Registration timing: **prospective**

Last update: **2023-01-23, 1401/11/03**
Update count: **0**

Registration date
2023-01-23, 1401/11/03

Registrant information

Name
Hesameddin Modir

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3313 9680

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he_modir@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of sedation and analgesia of ketorolac and diclofenac eye drops with tetracaine in cataract surgery

Public title
Comparison of anti-inflammatory eye drops in cataract surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cataract surgery candidate by Phaco method Obtaining informed consent for the intervention Age 35 to 85 years both sexes ASA class 1 and 2
Exclusion criteria:
Lack of patient permission Presence of mental disorders History of chronic use of sedatives Alcohol and drug use Having an allergy to the drugs used
Age
From **35 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into three groups by block method in the form of blocks of 3 or 6. Eligible patients will be assigned to three intervention groups in the order of entry and based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. To allocate the samples, the block randomization method with the size of 3 or 6 blocks will be used in such a way that by using the random number generation software, the randomization sequence will be generated according to the required sample size on three groups. All these works will be done with a software called Sealed Envelope. By using this method, concealment will be achieved . The concept of concealment is the unpredictability of assigning people to groups, which means that the researcher will not be able to predict which group the next person will be in. Therefore, patients will be divided into 3 equal groups using the block allocation method.
Blinding (investigator's opinion)
Double blinded
Blinding description
The eye drops used in groups are prepared and prescribed by an anesthesiologist who knows the type of drugs and groupings (the preparation of each drop is such that the container corresponding to each drop is covered with colored paper of a specific color so that the patients will not know the drop type used and the group in which they are placed) Also, the person collecting information who is a collaborator of the project is completely unaware of which group the patient is in, and the corresponding surgeon is also blinded to the drugs and groups. Also, all surgeries will be performed by one person.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Arak University of Medical Sciences
Street address
Vice President of Research and Technology, University Complex of the Prophet (PBUH),Arak City, Arak University of Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2022-12-11, 1401/09/20
Ethics committee reference number
IR.ARAKMU.REC.1401.260

Health conditions studied

1

Description of health condition studied
Postoperative pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
Postoperative pain
Timepoint
Every 5 minutes during surgery and recovery and 1, 2 and 4 hours after surgery
Method of measurement
Visual analogue scale

2

Description
Mean arterial pressure
Timepoint
Every 5 minutes until the end of the operation and during recovery
Method of measurement
non invasive blood pressure monitoring

3

Description
Heart rate
Timepoint
Every 5 minutes until the end of the operation and during recovery
Method of measurement
Cardiac monitoring

4

Description
The amount of sedation
Timepoint
Every 5 minutes during surgery and recovery and 1, 2 and 4 hours after surgery
Method of measurement
Ramsay scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: 0.5% tetracaine eye drops along with artificial tear drops, one drop each every 10 minutes during 30 minutes before the operation
Category
Treatment - Drugs

2

Description
First intervention group: 0.5% tetracaine eye drops along with 0.5% ketorolac drops, one drop each every 10 minutes during 30 minutes before the operation
Category
Treatment - Drugs

3

Description
Second intervention group: 0.5% tetracaine eye drops along with 0.1% diclofenac drops, one drop each every 10 minutes during 30 minutes before the operation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir Hospital
Full name of responsible person
Dr Hesameddin Modir
Street address
Amir Kabir Hospital, Arak hospital area next to Hamiyar Institute-Nurse Square,Shahid Shiroudi St.
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3819693181
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amirkabir-hospital@arakmu.ac.ir

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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr Hesameddin Modir

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Medical Education

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available