

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 86 3313 9680

Email address

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

Arak University of Medical Sciences

Full name of responsible person

Dr Mehdi Salehi

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Arak University Of Medical Science, Basij Square

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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

modir.he@gmail.com

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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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