

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial of comparing the effects of lidocaine injection and non-injection into the anterior chamber of the eye on pain reduction after cataract surgery with general anesthesia

Protocol summary

Summary

This study is a double-blind clinical trial because patients were anesthetized, and they were not aware of intraocular injection and evaluation was performed by an anesthesiologist who did not know the code of patients. The purpose of this study is to reduce postoperative pain after cataract surgery. Study patients consisted 48 male and female candidates for cataract surgery and cases with liver and kidney failure, hypothyroidism, hyperthyroidism, uncontrolled diabetes, or uncontrolled hypertension were excluded from the study. They were randomized completely into two groups (each one 24 cases) and both groups by the same drugs were placed under general anesthesia: midazolam 0.2 mg/kg, fentanyl 2 µg/kg, thiopental sodium 4 mg/kg, atracurium 0.05 mg/kg. In the study group after induction and washing and cutting the cornea to the anterior chamber, 0.1 mg of lidocaine 1% was injected and in the control group, lidocaine was not injected. Pain of the patients was evaluated based on the pain scale ranging from 0 to 10 just after their admission to recovery, and 1, 2, and 3 hours after their transition to the recovery. Moreover, their blood pressure, heart rate and complications such as itching was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072518589N1**

Registration date: **2015-03-16, 1393/12/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-16, 1393/12/25

Registrant information

Name

Fatemeh Zamani

Name of organization / entity

Ahvaz Jondishapour University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparing the effects of lidocaine injection and non-injection into the anterior chamber of the eye on pain reduction after cataract surgery with general anesthesia

Public title

Effect of lidocaine injection on postoperative pain of cataract surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: men and women with an age range of 20 to 80 years to undergo cataract surgery with general anesthesia. Exclusion criteria: liver and kidney failure, hypothyroidism, hyperthyroidism, uncontrolled diabetes, uncontrolled hypertension.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The table of random numbers used for randomization. Each patient is assigned a code by who does not know about the protocol of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jondishapour University of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jondishapour University of Medical Sciences, Golestan, Ahvaz

City

Ahvaz

Postal code

61946-46343

Approval date

2014-05-10, 1393/02/20

Ethics committee reference number

45. 1393. ajums. REC

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H25 ,H26

ICD-10 code description

Senile cataract and other cataract

Primary outcomes

1

Description

Pain

Timepoint

Admission to recovery, 1, 2, 3 hours after the transition to the recovery

Method of measurement

Questionnaire vas of 0 to 10

Secondary outcomes

empty

Intervention groups

1

Description

Group 1: Single injection of 0.1 mg of lidocaine 1% of Tehran pharmaceutical drug companies into the anterior chamber after being anesthetized patient. Group 2: no injection of lidocain.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Ahmadreza mohtadi

Street address

Imam Khomeini Hospital, Shahid Ahvazian St., Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jondishapour University of Medical Sciences, Golestan, Ahvaz

City
Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person
Fatemeh Zamani

Position
Resident Of Anesthesiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty