

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3222 1994

##### Email address

zamani.f@ajums.ac.ir

#### 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

##### City

Ahvaz

## 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

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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*