

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study the effect of intravenous lidocaine on intra ocular pressure in cataract surgical patients under sedation

Protocol summary

Summary

Ninety consecutive patients with ASA I, II who were candidate for cataract surgery were studied in a double blind randomized clinical trial. Patients' age range was 20-60 years. Patients with the history of heart blocks, taking anti IOP drugs and the ones who needed general anesthesia were excluded from the study. Patients were divided into two groups randomly. All patients received Sufentanyl 0.15 Mic/kg, 5 min before the operation and then their IOP were measured. Patients in group A received Lidocaine 2mg/kg, and IOP was measured 3min after the Lidocaine injection. Group B received placebo as the same way. Patients' heart rate, blood pressure and SPO2 were measured either.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811082946N2**
Registration date: **2010-01-28, 1388/11/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-01-28, 1388/11/08

Registrant information

Name

Mitra Yari

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2010-01-02, 1388/10/12

Expected recruitment end date

2010-04-02, 1389/01/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of intravenous lidocaine on intra ocular pressure in cataract surgical patients under sedation

Public title

Study the effect of intravenous lidocaine on Intra ocular pressure during cataract surgery while patients are given sedations

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with ASA I, II who were candidate for cataract surgery. Exclusion criteria: patients with history of heart blocks, taking anti IOP drugs and the ones who needed general anesthesia.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Kermanshah University of Medical Sciences

Street address

#2 building of medical university, shahid beheshti boulevard

City

Kermanshah

Postal code

6714415333

Approval date

2009-12-25, 1388/10/04

Ethics committee reference number

A/33917/j/25

Health conditions studied

1

Description of health condition studied

cataract surgery

ICD-10 code

H43.9

ICD-10 code description

Disorder of vitreous body, unspecified

Primary outcomes

1

Description

Intraocular pressure (IOP)

Timepoint

5 min before the operation and 3 min after injecting Lidocaine or placebo

Method of measurement

using Tonometer PT100 model protable non contact

Secondary outcomes

1

Description

patients' heart rate, blood pressure and SPO2

Timepoint

5 min before the operation and 3 min after injecting Lidocaine or the placebo

Method of measurement

using monitoring machine Passport II

Intervention groups

1

Description

Itravenous Lidocaine 2mg/kg

Category

Prevention

2

Description

normal saline (0.1 cc/kg)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Mitra Yari

Street address

Parastar boulevard, Sorkhalijeh

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Imam Reza Hospital, Parastar boulevard, Sorkhalijeh

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
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Position
assistant professor, anesthesiologist
Other areas of specialty/work
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Person responsible for updating data

Contact

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