

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of dexmedetomidine and lidocaine 2% in controlling analgesia and hemodynamic changes in cataract surgery with local anesthesia

Protocol summary

Study aim

Comparison of dexmedetomidine and lidocaine 2% in controlling analgesia and hemodynamic changes in cataract surgery with local anesthesia

Design

This study will be a double-blind randomized clinical trial with parallel groups on 52 patients referred to Motahhari Hospital in Jahrom who undergo cataract surgery. Patients participating in the study will be divided into two groups by tossing coins.

Settings and conduct

Patients referred to Motahhari Hospital in Jahrom who will undergo cataract surgery will be included in the study. Patients participating in the study will be divided into two groups of dexmedetomidine and lidocaine by throwing coins. The person participating in the study, the researcher and the data collector will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred to Motahhari Hospital in Jahrom who underwent cataract surgery and expressed their consent to participate in the study. Conditions of non-entry: includes patients with severe medical conditions to provide a suitable position in cataract surgery.

Intervention groups

Intervention group 1: They will receive 3 cc of lidocaine 2% retrobulbarly. Intervention group 2: 5 µg / kg dexmedetomidine + 3 cc lidocaine 2% will receive retrobulbar.

Main outcome variables

Pain, hemodynamic changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050976N7**

Registration date: **2021-08-28, 1400/06/06**

Registration timing: **prospective**

Last update: **2021-08-28, 1400/06/06**

Update count: **0**

Registration date

2021-08-28, 1400/06/06

Registrant information

Name

navid kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 6085

Email address

k.navid@juma.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-03-03, 1400/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of dexmedetomidine and lidocaine 2% in controlling analgesia and hemodynamic changes in

cataract surgery with local anesthesia

Public title

Comparison of dexmedetomidine and lidocaine 2% in controlling analgesia and hemodynamic changes in cataract surgery with local anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having surgical indications Indication of local anesthesia

Exclusion criteria:

The patient refuses local anesthesia even after careful consultation and explanation of the risks of this procedure Uncontrolled Parkinson's patient Patient with severe medical condition to limit the appropriate position in cataract surgery Patient with a history of severe reactions Allergy or other side effects to lidocaine or dexmedetomidine

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients participating in the present study were randomly divided into two groups by tossing coins.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding in the present study, the double-blind method is used, so that 1- the person who reviews the results and 2- the person who performs the injections, information about which patients received dextromethane or lidocaine alone, Do not have.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jahrom University of Medical

Sciences

Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

City

Jahrom

Province

Fars

Postal code

7167758256

Approval date

2021-08-23, 1400/06/01

Ethics committee reference number

IR.JUMS.REC.1400.031

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

E08.36

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic cataract

Primary outcomes

1

Description

Vital Signs

Timepoint

After retrobulbar block, one and two hours after the onset of retrobulbar block

Method of measurement

monitoring

2

Description

the pain

Timepoint

One and two hours of retrobulbar block

Method of measurement

VAS criteria

Secondary outcomes

1

Description

Intraocular pressure

Timepoint

Before and after retrobulbar block

Method of measurement

Tonometry

Intervention groups

1

Description

Intervention group 1: They will receive 3 cc of lidocaine 2% retrobulbarly.

Category

Treatment - Drugs

2

Description

Intervention group 2: 5 µg / kg dexmedetomidin + 3 cc lidocaine 2% will receive retrobulbar.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital of Jahrom city

Full name of responsible person

Navid Kalani

Street address

Jahrom, Shahid Motahari Boulevard, Peymanieh Hospital

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71677251542

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+98 71 3864 2580

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Navidkalani@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavous Solhjoo

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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

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Reza Sahraei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Anesthesiology

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Jahrom University of Medical Sciences

City

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Province**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

Not applicable

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