

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of intravenous lidocaine and dexamethasone on extubation time and postoperative complications in elderly patients undergoing vitrectomy: a randomized clinical trial

Protocol summary

Study aim

Determining the effect of lidocaine and dexamethasone intravenous injection on extubation time and postoperative complications in elderly patients undergoing vitrectomy.

Design

This study is a phase III, double-blind, randomized, parallel-group, control clinical trial that will be conducted on 60 patients aged 60 to 80 years, candidates for vitrectomy surgery under general anesthesia. Patients will be assigned to study groups using Random Allocation Software.

Settings and conduct

This study will be conducted at Feyz Hospital, Isfahan, on patients aged 60 to 80 years who are candidates for vitrectomy surgery under general anesthesia. In this double-blind study, participants, clinical caregivers, researchers, and the data collector will be blinded to the type of intervention. The study drugs (dexamethasone and lidocaine) will be prepared and injected in 2 cc syringes of identical appearance and volume by a nurse who is not involved in the data collection process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 60 to 80 years with ASA I-II, candidates for eye surgery under general anesthesia who consent to participate in the study. Exclusion criteria: Movement disorders; history of postoperative nausea and vomiting; receiving antiemetics, corticosteroids, or analgesics in the last 24 hours; sensitivity to study drugs; inability to communicate.

Intervention groups

In this study, patients were divided into two intervention groups (receiving intravenous dexamethasone at a dose of 0.1 mg/kg) and control group (receiving intravenous lidocaine at a dose of 1.5 mg/kg).

Main outcome variables

Extubation time; severity of cough and sore throat;

hoarseness; occurrence of nausea and vomiting; severity of pain and shivering after surgery; occurrence of laryngospasm; average length of stay in recovery;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N25**

Registration date: **2025-10-14, 1404/07/22**

Registration timing: **prospective**

Last update: **2025-10-14, 1404/07/22**

Update count: **0**

Registration date

2025-10-14, 1404/07/22

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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hamidshetabi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-06, 1404/08/15

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intravenous lidocaine and dexamethasone on extubation time and postoperative complications in elderly patients undergoing vitrectomy: a randomized clinical trial

Public title

The effect of intravenous lidocaine and dexamethasone injection on endotracheal tube removal time and quality of postoperative recovery in elderly patients.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range between 60 and 80 years Candidate for eye surgeries under general anesthesia Patient's informed consent to participate in the study ASA Class I-II

Exclusion criteria:

Having a history of allergies or known allergies to lidocaine, dexamethasone or other drugs used in the study protocol. Patients with a history of nausea and vomiting after surgery Taking strong painkillers (such as narcotics), anti-inflammatory drugs or corticosteroids or anti-nausea and vomiting before surgery. Existence of severe cognitive impairment (for example, advanced dementia), severe mental illness or lack of fluency in Persian, which makes it impossible to communicate and evaluate the criteria of outcomes (such as pain). Severe heart failure (less than 30% cardiac discharge fraction) Severe cardiac conduction disorders (such as second or third degree heart blocks) Severe liver failure (Cirrhosis of Child-P Class B or C) Severe renal failure (EGFR < 30 ml / min) Diseases neuromuscular (such as myasthenia gravis)

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Allocation Software will be used to allocate patients undergoing vitrectomy to either lidocaine (Group A) or dexamethasone (Group B). An eligible patient list will be created and numbered, and then randomization will be performed using blocks of 4. An independent person will maintain the confidentiality of

the allocation list throughout the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study , participants, caregivers, researchers, and data collectors will be blinded to the type of intervention and patient grouping. Patients are randomly assigned to receive either lidocaine or dexamethasone, the study drugs is prepared in 2 ml syringes of identical volume and appearance by a nurse who is not involved in the data collection process to ensure blinding and prevent disclosure of interventions.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Boulevard

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Postal code

8174673461

Approval date

2025-06-28, 1404/04/07

Ethics committee reference number

IR.MUI.MED.REC.1404.133

Health conditions studied**1****Description of health condition studied**

Ocular pain

ICD-10 code

H57.1

ICD-10 code description

Ocular pain

2**Description of health condition studied**

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

3

Description of health condition studied

cough

ICD-10 code

R05

ICD-10 code description

Cough

4

Description of health condition studied

Sore throat

ICD-10 code

J02

ICD-10 code description

Acute pharyngitis

5

Description of health condition studied

Extubation time

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Extubation time

Timepoint

From the time the anesthetic agent (isoflurane) is discontinued until the moment the tracheal tube is removed (Extubation)

Method of measurement

In minutes. Measurement method: Time recorded by stopwatch by a blinded assessor who was unaware of the patient's grouping.

2

Description

Postoperative Pain Intensity

Timepoint

Every 10 minutes during the patient's stay in recovery

Method of measurement

Using a Visual Analog Scale (VAS) from 0 (no pain) to 10 (the most severe pain possible)

Secondary outcomes

1

Description

Postoperative Nausea and Vomiting (PONV)

Timepoint

Every 10 minutes during the patient's stay in recovery

Method of measurement

Observational recording by the recovery ward nurse (blinded) and direct questioning of the patient.

2

Description

Rescue analgesic use

Timepoint

Every 10 minutes during the patient's stay in recovery

Method of measurement

Direct questioning of the patient.

3

Description

Rescue antiemetic use

Timepoint

Every 10 minutes during the patient's stay in recovery

Method of measurement

Observing and questioning the patient

4

Description

Length of stay in the recovery ward

Timepoint

Every 10 minutes during the patient's stay in recovery

Method of measurement

From the patient's entry into the recovery ward until they meet the criteria for discharge from recovery (Aldrete score ≥ 9).

5

Description

The patient's overall satisfaction with the quality of the recovery period after anesthesia.

Timepoint

At the end of their recovery stay

Method of measurement

Using a Likert scale (from 1 "very dissatisfied" to 5 "very satisfied").

6

Description

Drug-related side effects

Timepoint

Every 10 minutes during the patient's stay in recovery

Method of measurement

Observing and questioning the patient

Intervention groups

1

Description

Intervention Group: IV Lidocaine, Drug: Lidocaine 2% (20 mg/mL), Dose and Calculation Method: 1.5 mg/kg of patient body weight, Dose Cap: The maximum allowable dose is 100 mg, Injection Volume: The final calculated volume will be drawn into identical, indistinguishable 10 mL syringes, Injection Time: The drug is injected as a slow IV bolus over 3-5 minutes, prior to extubation.

Category

Treatment - Drugs

2

Description

Control/Comparison Group: Intravenous Dexamethasone, Drug: Dexamethasone (4 mg/mL), Dose and Calculation Method: 0.1 mg/kg of patient body weight, Dose Cap: The maximum allowable dose is 8 mg, Injection Volume: The final calculated volume will be drawn into identical, indistinguishable 10 mL syringes (same as the lidocaine group), Injection Time: The drug is injected as a slow IV bolus over 3-5 minutes, immediately after induction of general anesthesia and before the start of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faiz Hospital

Full name of responsible person

Hamidreza Shetababi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The participant data file, study protocol, clinical study report without individual patient data and statistical data will be published.

When the data will become available and for how long

The access period begins 6 months after publication of the article.

To whom data/document is available

Researchers from academic institutions will have access.

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Dr. Hamidreza Shatabi

What processes are involved for a request to access data/document

By email to the research manager:
hamidshetabi@med.mui.ac.ir

Comments