Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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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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Isfehan
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
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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
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Person responsible for updating data

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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