Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effects of intravenous oxytocin and lidocaine on hemodynamic responses during laryngoscopy and tracheal intubation in adult patients undergoing elective surgery: A triple-blind randomized controlled trial

Protocol summary

Study aim

The aim of this study is to compare the effectiveness of lidocaine and oxytocin in controlling hemodynamic responses including systolic, diastolic, and mean arterial pressure as well as heart rate following laryngoscopy and tracheal intubation in anesthetized patients undergoing elective surgery. The study seeks to determine which drug provides superior cardiovascular stability during airway manipulation.

Design

A randomized, double-blind, phase 3, parallel group clinical trial with 60 patients. Randomization will be performed using a random number table and sealed envelopes. Allocation concealment will be ensured.

Settings and conduct

The study will be conducted in a teaching hospital affiliated with the Alborz university of medical sciences (Shahid Madani). Eligible patients will be enrolled after obtaining informed consent. Medications will be administered by blinded clinical staff. Participants, care providers, and outcome assessors will remain blinded to group assignments.

Participants/Inclusion and exclusion criteria

Adult patients scheduled for elective surgery under general anesthesia; ASA class I or II; no history of cardiovascular disease or hypertension; no known allergy to lidocaine or oxytocin; not taking antihypertensive or psychoactive medications; not pregnant or lactating; willingness to provide informed written consent

Intervention groups

The first group will receive intravenous lidocaine at a specified dose 10 minutes before laryngoscopy and tracheal intubation. The second group will receive intravenous oxytocin at an equivalent dose during the same timeframe.

Main outcome variables

Changes in systolic, diastolic, and mean arterial blood pressure; changes in heart rate; incidence of arrhythmias following intubation

General information

Reason for update

Acronym

OL-HemoTrial (Oxytocin–Lidocaine Hemodynamic Trial)

IRCT registration information

IRCT registration number: **IRCT20250608066112N1**
Registration date: **2025-08-04, 1404/05/13**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-04, 1404/05/13**
Update count: **0**

Registration date

2025-08-04, 1404/05/13

Registrant information

Name
Vida Hafezi
Name of organization / entity
Alborz University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01

Expected recruitment end date
2025-09-21, 1404/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of intravenous oxytocin and lidocaine on hemodynamic responses during laryngoscopy and tracheal intubation in adult patients undergoing elective surgery: A triple-blind randomized controlled trial

Public title
Oxytocin versus lidocaine for controlling hemodynamic response during intubation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years Candidates for elective surgery requiring intubation and laryngoscopy ASA physical status class I and II Written informed consent for participation No contraindication to lidocaine or oxytocin No known allergy to standard anesthetic agents Systolic blood pressure >90 mmHg and heart rate >60 bpm
Exclusion criteria:
Pregnancy History of cardiovascular diseases (e.g. arrhythmia or tachycardia) Chronic respiratory diseases Neurological disorders Hepatic or renal disease History of substance abuse or stimulant use Anticipated difficult intubation (e.g. short neck, large tongue, small jaw) Known allergy to lidocaine or oxytocin
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple individual randomization will be used. The random allocation sequence will be generated using a computer-based random number generator. For allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) will be utilized. Each envelope will contain a coded drug vial, which will be prepared by an independent person not involved in the study. The envelopes will be handed to a nurse who will be unaware of the intervention type. Outcome assessors will also be blinded to the group allocation. No stratification will be applied, but age and gender balance between groups will be maintained as much as possible.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, participants, care providers (including the administering nurse), investigators, outcome assessors, and data analysts will be blinded to group assignments. The study medications (oxytocin and lidocaine) will be prepared in identical coded vials by an independent individual not involved in the study. Each participant’s assigned intervention will be placed in a sequentially numbered, opaque, sealed envelope (SNOSE) and handed to the nurse responsible for injection. The outcome parameters (blood pressure, heart rate, ECG changes, etc.) will be measured by assessors unaware of the treatment allocation. Group codes will remain concealed from all parties until after data analysis is completed, ensuring full triple-blinding.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Alborz University of Medical Sciences
Street address
Alborz University of Medical Sciences, Taleghani Sq., North Taleghani Blvd.
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Province
Alborz
Postal code
3149779453
Approval date
2025-05-24, 1404/03/03
Ethics committee reference number
IR.ABZUMS.REC.1404.065

Health conditions studied

1

Description of health condition studied
Hemodynamic responses to laryngoscopy and endotracheal intubation under general anesthesia
ICD-10 code
R00.1

ICD-10 code description
Bradycardia, unspecified

Primary outcomes

1

Description
Change in patients' systolic blood pressure following endotracheal intubation
Timepoint
Systolic blood pressure will be measured before administration of intervention, immediately before endotracheal intubation, and at one, three, and five minutes after intubation
Method of measurement
Systolic blood pressure will be measured using a non-invasive hospital-grade blood pressure monitor

2

Description
Change in patients' diastolic blood pressure following endotracheal intubation
Timepoint
Before intervention, immediately before intubation, and at one, three, and five minutes after intubation
Method of measurement
Measured using a non-invasive hospital-grade blood pressure monitor

3

Description
Change in patients' heart rate following endotracheal intubation
Timepoint
Before intervention, immediately before intubation, and at one, three, and five minutes after intubation
Method of measurement
Measured using hospital electrocardiographic heart rate monitor

Secondary outcomes

1

Description
Occurrence of cardiac arrhythmias following endotracheal intubation in patients receiving lidocaine or oxytocin
Timepoint
From the beginning of intervention up to five minutes after intubation
Method of measurement
Continuous monitoring using hospital electrocardiographic system

2

Description
Change in mean arterial blood pressure (MAP) following endotracheal intubation
Timepoint
Before intervention, immediately before intubation, and at one, three, and five minutes after intubation
Method of measurement
Calculated from systolic and diastolic values measured using a non-invasive monitor

Intervention groups

1

Description
Intervention group: Patients in this group will receive lidocaine at a dose of 1.5 mg per kilogram of body weight administered as a slow intravenous injection one to two minutes prior to endotracheal intubation. The lidocaine solution will be 2% lidocaine hydrochloride manufactured by Caspian Pharmaceutical Company. The injection will be performed by a nurse anesthetist who will be blinded to the group assignment of the patient.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in this group will receive magnesium sulfate at a dose of 30 mg per kilogram of body weight, administered as an intravenous infusion over 10 minutes, starting one to two minutes before endotracheal intubation. The magnesium sulfate solution used will be 20% concentration manufactured by Shahid Ghazi Pharmaceutical Company. The infusion will be administered by a nurse anesthetist who is blinded to the patient's group assignment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Educational and Medical Center
Full name of responsible person
Dr.Mahdi Rezaei
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Karaj - Taleghani Intersection - Mahan Boulevard - Corner of Shahid Madani Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Alborz 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
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Mahdi Rezai
Position
Professor
Latest degree
Specialist
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Anesthesiology
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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Individual participant data (IPD), study protocol, informed consent form, statistical analysis plan, clinical study report, statistical analysis codes, and data dictionary; all documents will be anonymized and made available after completion of the trial.

When the data will become available and for how long
Data and documents will be available starting 6 months after the publication of the final manuscript, for a period of 5 years.

To whom data/document is available
Academic researchers, investigators from recognized research institutions, PhD and post-doctoral students for independent academic research.

Under which criteria data/document could be used
Use is limited to independent academic analysis with a sound methodological proposal. Commercial use or redistribution of the data is prohibited without written permission.

From where data/document is obtainable
Requests should be sent to the corresponding author of the study, Dr. Mehdi Rezaei.

What processes are involved for a request to access data/document
The request will undergo initial screening. Upon approval, a data confidentiality agreement will be issued. Once signed, access will be granted within 10 working days.

Comments