Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the Effect of Xylapy cream 5% on Postoperative Sore Throat in Adults Following General Anesthesia with a Laryngeal Mask Airway: A Double-Blind Clinical Trial Study"

Protocol summary

Study aim

Investigating the Effect of Xylapy cream 5% on Postoperative Sore Throat in Adults Following General Anesthesia with a Laryngeal Mask Airway

Design

A phase 2-3, randomized, double-blind, parallel-group, controlled clinical trial involving 300 patients. Randomization will be performed using the rand function of Excel software.

Settings and conduct

Anesthesia candidates referred to Firoozgar and Hasheminejad hospitals in Tehran will be included in the study and randomly assigned to intervention and control groups. This study will be conducted in a double-blind manner so that the outcome assessor and analyst will be blind to the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adult patients of both genders, aged 18 to 65 years, classified as ASA (American Society of Anesthesiologists) physical status I and II, who are candidates for surgery lasting 1 to 3 hours under general anesthesia with a laryngeal mask airway (LMA). Exclusion Criteria: Known hypersensitivity to local anesthetics (LA); more than two attempts required for LMA insertion; patients undergoing head and neck surgeries involving the airway; airway injuries; preoperative pharyngeal pain; congenital oral anomalies; loose or artificial dentures; anticipated difficult airway.

Intervention groups

Intervention: Zylapril 5% cream (2.5% lidocaine + 2.5% prilocaine, Tehran Chemi) applied to the pharyngeal mask cuff. Control: No anesthetic administered. The anesthesia protocol (midazolam, fentanyl, lidocaine, propofol, isoflurane), mask size/pressure, placement attempts (max 2), and extubation time will be the same for everyone. Patients are initially hospitalized in the recovery room for one hour after surgery and examined for sore throats once during this time and once after hospitalization in the ward .

Main outcome variables

Postoperative cough; Postoperative voice change; Sore throat; Hypoxia;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250421065412N1**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date

2025-05-29, 1404/03/08

Registrant information

Name

Sina Forghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 2530

Email address

drsinaforghani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2025-09-06, 1404/06/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Xylapy cream 5% on Postoperative Sore Throat in Adults Following General Anesthesia with a Laryngeal Mask Airway: A Double-Blind Clinical Trial Study"

Public title
The Effect of Xylapy cream 5% on Postoperative Sore Throat in Adults
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients of both genders, aged 18 to 65 years, classified as ASA (American Society of Anesthesiologists) physical status I and II, who are candidates for surgery lasting 1 to 3 hours under general anesthesia with a laryngeal mask airway
Exclusion criteria:
Known hypersensitivity to local anesthetics More than two attempts required for Laryngeal Mask Airway insertion. Patients undergoing head and neck surgeries involving the airway. Airway injuries Preoperative pharyngeal pain Congenital oral anomalies. Loose or artificial dentures Anticipated difficult airway.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the block random allocation method will be employed. First, the randomization sequence will be generated before the study commences and patient recruitment, ensuring that the initial blocks containing 4 parts are created by considering all possible allocation scenarios for the intervention group (I) and control group (C) within each block (such as I-I-C-C, I-C-I-C, etc.). Then, the created blocks will be randomly numbered using the Excel RAND function. After sorting the numbers from smallest to largest, the order of block selection will be determined, and we will proceed to select the blocks. Block selection will continue until the required sample size is reached. To conceal the allocation, the treatments will be coded and placed in sealed envelopes. These envelopes will be opened only after the patient is registered in the study. In each block, 4 allocations (2 cases in the intervention group and 2 cases in the control group) will occur, and this process will continue until the target sample size is met.
Blinding (investigator's opinion)
Double blinded
Blinding description
Since the treatment methods used are unnamed and will be identified by specific codes, the outcome assessor and analyst will remain blinded to the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Medicine, Iran University of Medical Sciences
Street address
Iran University of Medical Sciences,next to Milad Tower,Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
14496-14535
Approval date
2025-02-03, 1403/11/15
Ethics committee reference number
IR.IUMS.FMD.REC.1403.573

Health conditions studied

1

Description of health condition studied
Anesthesia methods in surgeries
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Postoperative sore throat rate
Timepoint
Patients will be assessed for the incidence and severity of postoperative sore throat at two times: once after surgery and during recovery, and a second time 3 hours

after surgery.

Method of measurement

Using a Likert scale that divides severity into category 1: mild; category 2: moderate; category 3: severe

2

Description

Coughing after surgery

Timepoint

After surgery in recovery and 3 hours after surgery,

Method of measurement

Questioning the patient

3

Description

Voice change after surgery

Timepoint

After surgery in recovery and 3 hours after surgery,

Method of measurement

Questioning the patient

4

Description

Hypoxia

Timepoint

After surgery in recovery and 3 hours after surgery

Method of measurement

Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, Zylapril 5% cream (a topical anesthetic combining 2.5% lidocaine + 2.5% prilocaine, manufactured by Tehran Chemi Pharmaceutical Company) will be applied once to the cuff of their laryngeal airway mask. The anesthesia protocol included midazolam (0.03–0.05 mg/kg), fentanyl (3 mcg/kg), lidocaine (1 mg/kg), and propofol (2–3 mg/kg), with anesthesia maintained using isoflurane (MAC 1.5). The size of the airway mask was selected based on the patient's weight, and the material and manufacturer of the mask were standardized for all patients.

Category

N/A

2

Description

Control Group: No local anesthetic agent will be applied to the cuff of their laryngeal airway mask (LMA). The anesthesia protocol included midazolam (0.03–0.05 mg/kg), fentanyl (3 mcg/kg), lidocaine (1 mg/kg), and propofol (2–3 mg/kg), with anesthesia maintained using isoflurane (MAC 1.5). The size of the airway mask was determined based on the patient's weight, and the material and manufacturer of the mask will be standardized for all patients.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firuzgar Hospital

Full name of responsible person

Sina Forghani

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Sina forghani

Position
Anesthesia resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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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
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

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

Not applicable