Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the incidence of laryngospasm after removal of the laryngeal mask airway (LMA) using two methods coated with lidocaine gel and coated with plain lubricant in pediatric patients presenting to the hospital

Protocol summary

Study aim

Comparison of the incidence of laryngospasm after removal of the laryngeal mask airway (LMA) in two methods: coated with lidocaine gel and coated with plain lubricant in children visiting Mofid Children's Hospital in Tehran

Design

A randomized, single-blind, phase 3 clinical trial with a control group, parallel groups, conducted on 60 patients.

Settings and conduct

This study will be conducted as a single-blind (outcomes assessor blinded) trial on pediatric patients scheduled for elective surgery using a laryngeal mask (LMA) as the method of airway support during the operation at Mofid Hospital in Tehran. In the first group, LMA insertion will be performed using a simple lubricant gel, and in the second group, it will be performed using lidocaine gel. The anesthesia induction method will be the same for both groups and will include 1-2 mg/Kg midazolam, 0.02 mg/Kg fentanyl, 2-5 mcg/Kg propofol, and 0.1-0.2 mg/Kg cisatracurium. Anesthesia maintenance will be achieved using sevoflurane. Intraoperative monitoring will be carried out using routine monitoring including electrocardiography, pulse oximetry, non-invasive blood pressure measurement, and capnography.

Participants/Inclusion and exclusion criteria

Inclusion criteria: American Society of Anesthesiologists (ASA) class one, candidate for surgery with laryngeal airway mask placement, parental consent to participate in the study, child weight between 5 and 20 kilograms. Exclusion criteria: patient unwillingness to participate in the research project.

Intervention groups

In the control group, laryngeal airway mask insertion will be performed using simple lubricant gel (Paliz Teb lubricating gel, Iran). In the intervention group, laryngeal airway mask insertion will be performed using lidocaine gel (Xylogel 2%, Sinadaroo, Iran)

Main outcome variables

Laryngospasm, Cough during recovery, Cough within the first 12 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250116064403N1**
Registration date: **2026-05-06, 1405/02/16**
Registration timing: **prospective**

Last update: **2026-05-06, 1405/02/16**
Update count: **0**

Registration date

2026-05-06, 1405/02/16

Registrant information

Name

Seyed Alireza Mahdavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date
2026-12-22, 1405/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the incidence of laryngospasm after removal of the laryngeal mask airway (LMA) using two methods coated with lidocaine gel and coated with plain lubricant in pediatric patients presenting to the hospital

Public title
Occurrence of laryngospasm in pediatric patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
American Society of Anesthesiologists (ASA) Physical Status Classification System: Class 1 Candidates undergoing surgery with Laryngeal Mask Airway (LMA) insertion Parental consent for participation in the study Pediatric weight between 5 to 20 kg
Exclusion criteria:
The duration of the surgery more than 2 hours Bleeding that leads to blood transfusion during surgery Surgical complication leading to severe hemodynamic instability of the patient during surgery Airway problems such as obstruction
Age
To **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed using permuted block randomization. For this purpose, two treatment groups (A and B) were defined, and possible block arrangements included AB and BA. Random numbers ranging from 0 to 9 were assigned, where numbers 0–4 corresponded to block AB and numbers 5–9 corresponded to block BA. Subsequently, the sequence of blocks was generated by selecting random numbers from a random number table. For instance, if the selected number corresponded to block AB, the first participant assigned to this block received treatment A, and the second participant received treatment B. Participants who met the inclusion criteria and provided informed consent were enrolled sequentially into the study. Each participant was assigned a unique study identification number according to their order of entry into the study, and their treatment group allocation was determined based on the pre-generated randomization list. To mitigate the predictability of group allocation due to small block sizes, the randomization list was generated prior to the commencement of the study by an independent, blinded individual not involved in the treatment team, and larger block sizes were utilized. Allocation concealment was rigorously maintained until the moment of assignment.
Blinding (investigator's opinion)
Single blinded
Blinding description
the outcome assessor and the statistical data analyst will be blinded to group allocation. For this purpose, patient information will be provided to the outcome assessor and the statistical analyst in a coded format, and they will not have access to information regarding the type of intervention. Data analysis will be conducted solely based on the assigned codes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Medicine, Shahid Beheshti University of Medical Sciences
Street address
Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
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Tehran
Province
Tehran
Postal code
1956944413
Approval date
2025-10-08, 1404/07/16
Ethics committee reference number
IR.SBMU.MSP.REC.1404.383

Health conditions studied

1

Description of health condition studied
Laryngospasm
ICD-10 code
J38.5
ICD-10 code description
Laryngeal spasm

Primary outcomes

1

Description
Laryngospasm
Timepoint
During extubation of the laryngeal airway mask
Method of measurement
standardized laryngospasm grading scale

2

Description
Cough
Timepoint
After transferring the patient to recovery and 12 hours after the end of surgery
Method of measurement
Cough Severity Grading Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:. In the intervention group, LMA insertion will be performed using lidocaine gel (Xylogel 2%, Sinadaroo, Iran)
Category
Treatment - Other

2

Description
Control group: In the control group, LMA insertion will be performed using simple lubricant gel (Paliz Teb lubricating gel, Iran).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Hospital
Full name of responsible person
Seyed Alireza Mahdavi
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Before reaching Mirdamad Street, Dr. Ali Shariati Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti 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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza Mahdavi
Position
Assisstant Professor
Latest degree
Subspecialist
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
Undecided - It is not yet known if there will be a plan to make this available