

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

City

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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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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

Assistant 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