

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 21 2205 5526

##### Email address

alirezamahdavi@sbmu.ac.ir

##### Recruitment status

**Not yet 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**

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

##### Street address

Before reaching Mirdamad Street, Dr. Ali Shariati Street

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۵۵۱۴۱۵۴۶۸

##### Phone

+98 21 2222 7029

##### Email

alirezamahdavi@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

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##### Province

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##### Phone

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##### Email

zarghi@sbmu.ac.ir

#### 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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**Person responsible for scientific 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**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Alireza Mahdavi

**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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**Phone**

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**Fax****Email**

alirezamahdavi@sbmu.ac.ir

**Web page address****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