

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of standard and lateral methods of laryngeal mask airway insertion in pediatric airway management (Number of attempts to insert laryngeal mask, mucosal damage, duration of laryngeal mask insertion, airway pressure and chest movement)

#### Protocol summary

Mucosal damage, Airway pressure, Duration of laryngeal mask implantation, Chest movement

#### Study aim

Comparison of standard and lateral methods of laryngeal mask airway insertion in pediatric airway management (Number of attempts to insert laryngeal mask, mucosal damage, duration of laryngeal mask insertion, airway pressure and chest movement)

#### Design

In a concealed, randomized, double-blinded, controlled clinical trial with a parallel-group design of 68 patients, simple randomization took place (Box of numbers)

#### Settings and conduct

This study was performed in Shahid Motahari Hospital in Urmia to investigate the effect of laryngeal masks on airway management (Number of attempts to insert laryngeal mask, mucosal damage, duration of laryngeal mask insertion, airway pressure and chest movement) of patients undergoing elective inguinal hernia repair surgeries study as randomized double-blinded, controlled clinical trial patients and their parents were unaware of being in the intervention groups and a clinical evaluation was performed on the placement of patients in the study groups who were unaware

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children between two and six years old, Candidate for elective hernia repair surgery with ASA1 and ASA2 under general anesthesia. Exclusion criteria: ASA3 patients and above and children with upper airway infections, mouth opening limitation, children with congenital heart disease, as well as patients undergoing emergency surgery who are at risk of aspiration of gastric contents.

#### Intervention groups

In the first group, the laryngeal mask was standardized, and in the second group, it was installed in lateral.

#### Main outcome variables

Number of attempts to implant a laryngeal mask,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170516033992N6**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

##### Registration date

2021-01-06, 1399/10/17

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3222 2010

##### Email address

karami.t@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-15, 1399/06/25

##### Expected recruitment end date

2021-03-15, 1399/12/25

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of standard and lateral methods of laryngeal mask airway insertion in pediatric airway management (Number of attempts to insert laryngeal mask, mucosal damage, duration of laryngeal mask insertion, airway pressure and chest movement)

**Public title**

Comparison of laryngeal mask insertion in pediatric airway management

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients candidates for selective inguinal hernia repair surgery ASA1 and ASA2 Obtaining informed consent

**Exclusion criteria:**

ASA3 and higher patients ??? Children with upper airway infections Limitation of mouth opening Children with congenital heart disease Patients undergoing emergency surgery who are at risk of aspiration of gastric contents

**Age**

From **2 years** old to **6 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, simple randomization took place in a way that numbers from 1 to 68 were written separately on paper pieces and put inside a blinded box. For each patient, a piece of paper was drawn out. If the number drawn for the patient was even it went to group A and if it was an odd number, patients were attributed to group B.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and their parents were unaware of being in the intervention groups and the clinical evaluator was unaware of the placement of patients in the study groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

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No30., Jihad Sq., Resalat St., Urmia University of Medical Sciences, Urmia, Iran

**City**

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**Province**

West Azarbaijan

**Postal code**

5715833631

**Approval date**

2020-09-13, 1399/06/23

**Ethics committee reference number**

IR.UMSU.REC.1399.188

**Health conditions studied****1****Description of health condition studied**

Inguinal hernia

**ICD-10 code**

K40

**ICD-10 code description**

Inguinal hernia

**Primary outcomes****1****Description**

Chest movement

**Timepoint**

Through anesthesia procedure in the operation room

**Method of measurement**

Observation (No movement, Partially good, Adequately good)

**2****Description**

Airway pressure

**Timepoint**

Through anesthesia procedure in the operation room

**Method of measurement**

Adjustable Pressure Limiting results

**3****Description**

Time of Laryngeal mask insertion

**Timepoint**

Through anesthesia procedure in the operation room

**Method of measurement**

Clock

**4****Description**

Mucous damage

**Timepoint**

After extracting the mask

**Method of measurement**

presence of blood on the mask

**5****Description**

Times tried to put the laryngeal mask on

**Timepoint**

In time of getting the mask

**Method of measurement**

Observation

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In the lateral method, the anesthetized patient's head is held with one hand, and the proximal part of the mask is inserted into the oral cavity with the same standard method so that the entire cuff is placed inside the mouth. Then rotate 45 degrees to the side so that only the side of the tongue is in contact with the side edge of the mask. Then use your thumb and forefinger to push the mask forward as much as possible to feel resistance to it. The mask is then rotated 45 degrees in the opposite direction of the previous rotation and placed in the midline position. Then, its cuff was filled to the standard size with a special manometer and its leakage was checked

**Category**

Treatment - Devices

**2****Description**

Control group: In the standard method, the anesthetized patient's head is held with one hand, the proximal part of the laryngeal mask is inserted into the oral cavity with the same standard method so that all the cuffs are inside the mouth. Then, we insert the airway mask into the mouth by the head extension. Next, we push the laryngeal mask using thumb and forefinger forward as much as possible to feel resistance. The mask is then placed in the midline position, and the cuff is filled to the standard size with a special manometer and leaks are checked. In this method, we do not rotate the head 45 degrees and according to the usual procedure, the

laryngeal mask is inserted as routine.

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Motahhari Hospital

**Full name of responsible person**

Tohid Karami

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karami.tohid@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Iraj Mohebbi

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mohebbi\_iraj@yahoo.co.uk

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Tohid Karami

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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

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**Full name of responsible person**

Oroumia University of Medical Sciences

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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**

Undecided - It is not yet known if there will be 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**

Information can be provided without patients' names

**When the data will become available and for how long**

1 year after completion of the study

**To whom data/document is available**

Faculty researchers

**Under which criteria data/document could be used**

Just for research targets

**From where data/document is obtainable**

Sending an email to Dr. Tohid Karami by academic researchers for sending anonymous data that takes about 2 weeks karami.tohid@gmail.com

**What processes are involved for a request to access data/document**

Just sending an email to DR. Tohid Karami

karami.tohid@gmail.com

**Comments**

