

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of standard and reverse methods of laryngeal mask airway insertion in pediatric airway management

#### Protocol summary

##### Study aim

Comparison of standard and reverse methods of laryngeal mask airway insertion in pediatric airway management

##### Design

A concealed, randomized, One-way 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 anesthesia on laryngeal masks on patients undergoing elective inguinal hernia repair surgery.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children between six months and fifteen years old, weight 5 to 70 kg, candidates for elective inguinal hernia repair surgery with ASA 1 and ASA2 under general anesthesia Exclusion criteria: ASA3 patients and above, emergency surgery patients 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 reverse.

##### Main outcome variables

Number of attempts to implant a laryngeal mask, Mucosal damage, Airway pressure, Duration of laryngeal mask implantation, Chest movement

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170516033992N3**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **retrospective**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

##### Registration date

2020-10-28, 1399/08/07

##### 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

2019-07-23, 1398/05/01

##### Expected recruitment end date

2020-01-21, 1398/11/01

##### Actual recruitment start date

2019-07-23, 1398/05/01

##### Actual recruitment end date

2020-01-20, 1398/10/30

##### Trial completion date

2020-01-20, 1398/10/30

##### Scientific title

Comparison of standard and reverse methods of laryngeal mask airway insertion in pediatric airway management

##### Public title

Comparison of laryngeal mask insertion in pediatric airway management

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

elective herniorrhaphy candidates with ASA1 and ASA2

Given permission to participate in the study

**Exclusion criteria:**

ASA3 and higher patients patients who require urgent surgery required with the risk of aspiration from the stomach fluids patients with full stomach and therefore with higher risk of aspiration of fluids

**Age**

From **6 months** old to **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **68**

Actual sample size reached: **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 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)**

Single blinded

**Blinding description**

The condition of the study was explained to patients but they weren't told which group they were categorized into. Other than our patients everyone in the patient care team including the doctor, research team, and analyzing and supervising team were informed about the intervention of each patient.

**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

**Street address**

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

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715833631

**Approval date**

2019-05-19, 1398/02/29

**Ethics committee reference number**

IR.UMSU.REC.1398.048

**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

### 1

#### Description

Chest movement

#### Timepoint

Through anesthesia procedure in the operation room

#### Method of measurement

Observation (no movement, partially good, adequately enough)

## Intervention groups

### 1

#### Description

Intervention group: Putting the mask upside down (Holding LMA from the proximal part, the mask was put inversely on the hard palate and was lead into the hypopharynx. then with a rotation of 180-degree counterclockwise, it was lead to the pharynx.

#### Category

Treatment - Devices

### 2

#### Description

Control group: standard laryngeal mask insertion (LMA mask was taken out completely and like holding a pen in the hand it was put inside the mouth and with pressing the index finger, it is lead toward the hard palate, pharynx and larynx.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Urmia Shahid Motahari University Hospital

##### Full name of responsible person

Tohid Karami

##### Street address

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#### Email

karami.tohid@gmail.com

#### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Iraj Mohebbi

##### Street address

No30., Jahad Sq., Resalat St., Uremia University of Medical Sciences, Uremia, Iran

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##### Phone

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##### Email

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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## Person responsible for scientific inquiries

### Contact

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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**  
Oroumia University of Medical Sciences

### Full name of responsible person

Tohid Karami

### Position

Assistant professor

### Latest degree

Subspecialist

### Other areas of specialty/work

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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