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

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

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
Street address
No30., Jahad Sq., Resalat St., Urmia University of Medical Sciences, Urmia, Iran
City
Urmia
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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No30., Jahad Sq., Resalat St., Urmia University of Medical Sciences, Urmia, Iran
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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, Urmia, Iran
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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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Person responsible for updating data

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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