Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
Comparison of standard and reverse methods of laryngeal mask airway insertion in pediatric airway managment

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)
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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 managment

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Iraj Mohebbi
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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
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
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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