

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of using supraglottic airway and classic laryngeal mask among children underwent surgery with general anesthesia

Protocol summary

Summary

This study will be conducted to compare the impact of the use of supraglottic airway and classic laryngeal mask in children undergoing surgery with general anesthesia. This randomized trial will study 60 children aged six months to six years undergoing elective hernia or hydrocele surgery referred to Dr. Sheikh Hospital in Mashhad, Iran. The patients randomly will be divided into two groups of 30 subjects (intervention and control group). The main inclusion criteria: children aged six months to six years old undergoing hernia or hydrocele in supine position. Exclusion criteria: intraoperative problems; problems during tracheal intubation; prolonged surgery. During anesthesia for tracheal intubation, supraglottic airway will be used for intervention group and classic laryngeal mask for control group. Finally, intraoperative indicators (blood on the device, maximum airway pressure, end-tidal CO₂) and postoperative complications in recovery (cough, sore throat, nausea, vomiting, dyspnea, dysphagia) will be compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091726858N4**
Registration date: **2016-10-08, 1395/07/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-08, 1395/07/17

Registrant information

Name

Toktam Kianian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of using supraglottic airway and classic laryngeal mask among children underwent surgery with general anesthesia

Public title

Comparison of the effects of using supraglottic airway and classic laryngeal mask among children underwent surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the age of six months to six years; elective hernia or hydrocele surgery in supine position;

no respiratory diseases and airway problems; no obstructive sleep apnea; no regurgitation; non-emergency surgery; no history of surgery on the abdomen and chest and BMI less than 30. Exclusion criteria: problems during surgery; problems during tracheal intubation and prolonged surgery (more than one hour).

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghorayshi Building, Daneshgah Street, Mashhad University of Medical Sciences

City

Mashhad

Postal code

9138813944

Approval date

2016-08-27, 1395/06/06

Ethics committee reference number

IR.MUMS.fm.REC.1395.60

Health conditions studied

1

Description of health condition studied

hernia

ICD-10 code

K40,K40.0,

ICD-10 code description

Inguinal hernia, Bilateral inguinal hernia, with obstruction, without gangrene, Bilateral inguinal hernia, with gangrene, Bilateral inguinal hernia, without obstruction or gangrene, Unilateral or unspecified inguinal hernia, with obstruction, without gang

2

Description of health condition studied

hydrocele

ICD-10 code

N43.3

ICD-10 code description

hydrocele of spermatic cord, testis or tunica vaginalis

Primary outcomes

1

Description

Maximum airway pressure

Timepoint

Intraoperative

Method of measurement

Ventilator

2

Description

Blood on equipment

Timepoint

Intraoperative

Method of measurement

Observation

3

Description

Sore Throat

Timepoint

Postoperative

Method of measurement

Interviews with patients

4

Description

End-Tidal CO2

Timepoint

Intraoperative

Method of measurement

Ventilator

5

Description

Cough

Timepoint

Postoperative

Method of measurement

Observation and interviews with patients

6

Description

Nausea

Timepoint

Postoperative

Method of measurement

Interviews with patients

7

Description

Vomit

Timepoint

Postoperative

Method of measurement

Interviews with patients

8

Description

Shortness of breath

Timepoint

Postoperative

Method of measurement

Interviews with patients

9

Description

Dysphagia

Timepoint

Postoperative

Method of measurement

Interviews with patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the proper depth of anesthesia, appropriate size of supraglottic airway based on the child weight and the manufacturer's instructions will be selected and placed by an anesthesiologist with experience in placement of supraglottic equipment.

Category

Prevention

2

Description

Control group: in the proper depth of anesthesia, appropriate size of classic laryngeal mask based on the child weight and the manufacturer's instructions will be selected and placed by an anesthesiologist with experience in placement of supraglottic equipment.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Shaikh Hospital

Full name of responsible person

Dr Mohammad Garavi Fard

Street address

Taheri Street, Touhid Square, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Department of pharmaceuticals, School of pharmacy, Pardis of University, Azadi Square, Mashhad,

City

Mashhad

Grant name

1

Grant code / Reference number

1

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Fatihe Kerman Saravi

Position

MSc

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty