

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 CO<sub>2</sub>) 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

Zahedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3344 1415

##### Email address

drnm@zaums.ac.ir

##### 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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## Person responsible for updating data

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## Person responsible for scientific inquiries

### Contact

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Mashhad university of medical sciences

**Full name of responsible person**

Dr Shahram Amini

**Position**

ICU fellowship, anesthesiologist

**Other areas of specialty/work****Street address**

Emam Reza hospital, Emam Reza square, Ebne Sina street

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Mashhad

**Postal code****Phone**

+98 51 3802 2314

**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*