

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the incidence of post operative nausea and vomiting and laryngospasm in controlled ventilation or spontaneous respiration in children underwent elective inguinal or femoral hernia surgery with general anesthesia

Protocol summary

Summary

Laryngospasm and postoperative nausea and vomiting (PONV) are serious complications after surgery in pediatric anesthesia and may lead to some morbidity like pulmonary aspiration. The objective of this randomized, single-blind, single-center study is to compare the incidence of laryngospasm and PONV in children undergoing general anesthesia with two methods of ventilation, control ventilation or spontaneous respiration. Two hundreds children aged 2-7 years who underwent inguinal or femoral hernia surgery will randomly (according to random number table) participate in this study. The patients will be unaware of the type of interventions. The patients with history of asthma; Fever; Morbid obesity; Cardiac disease; Metabolic disease; Renal disease; Electrolyte imbalance; and SpO₂ under %85 will not be included in this study. Exclusion criteria: respiratory complication in the time of intubation. Anesthesia will be induced with fentanyl 1microg/Kg, and thiopentone 4mg/Kg in all patients. In control ventilation group, atracurium will be injected as muscle relaxant before intubation. After intubation , the tidal volume will be set as 8-10 ml/kg and respiratory rate between 14-16 rate/minute. In spontaneous respiration (SR) group, after increasing the dose of halothane (1-4%), when the optimal depth of anesthesia will be established, the patients will be intubated, and the anesthetic gas will be delivered to patients by a Mapelson system. In the time of surgery, halothane 1-2% in N₂O/O₂ will be delivered to all patients as anesthetic agents. At the end of surgery, the muscle relaxant will be antagonized with neostigmine 50 microgram per kilogram-atropine 25 microgram per kilogram in control ventilation group, but these drugs will not be needed in patients in spontaneous respiration group. The incidence of post operative, nausea,

vomiting, laryngospasm in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072410385N1**

Registration date: **2013-02-04, 1391/11/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-04, 1391/11/16

Registrant information

Name

Ali Shahriari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the incidence of post operative nausea and vomiting and laryngospasm in controlled ventilation or spontaneous respiration in children underwent elective inguinal or femoral hernia surgery with general anesthesia

Public title
Comparison of controlled and spontaneous respiration on postoperative nausea and vomiting and laryngospasm in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: children admitted for elective inguinal or femoral hernia surgery. Exclusion criteria: History of asthma; Fever; Morbid obesity; Cardiac disease; Metabolic disease ; Renal disease; Electrolyte imbalance; SpO2 under %85

Age
From **2 years** old to **7 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University Of Medical Sciences
Street address
Qods St, Keshavarz Blvd
City

Tehran
Postal code
Approval date
2012-12-30, 1391/10/10
Ethics committee reference number
2482-130-91-3

2

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University Of Medical Sciences
Street address
Yemen St. Shahid Chamran Highway.
City
Tehran
Postal code
Approval date
2009-01-29, 1387/11/10
Ethics committee reference number
105/D.M

Health conditions studied

1

Description of health condition studied
Elective inguinal or femoral hernia
ICD-10 code
K40.2, K40
ICD-10 code description
Bilateral inguinal hernia, without obstruction or gangrene, Unilateral or unspecified inguinal hernia, without obstruction or gangrene, Bilateral femoral hernia, without obstruction or gangrene, Unilateral or unspecified femoral hernia, without obstructio

Primary outcomes

1

Description
Nausea
Timepoint
Every 15 minutes to 6 hours after the end of the intervention
Method of measurement
Questionnaire

2

Description
Vomiting
Timepoint
Every 15 minutes to 6 hours after the end of the intervention
Method of measurement
Questionnaire

3

Description

laryngospasm

Timepoint

Every minute to 30 minutes after the end of intervention

Method of measurement

Pulse oxymetry device

Secondary outcomes

empty

Intervention groups

1

Description

In spontaneous respiration group, after primary monitoring with ECG, SpO₂ and NIBP and after induction of anesthesia with intra-venous fentanyl 1microg/Kg (Rotex Medica Manufactory), thiopentone 4mg/Kg (Rotex Medica Manufactory) and after increasing the dose of inhalation halothane (from 1 to 4%) (Nicholas Piramal India Manufactory) and when the optimal depth of anesthesia will be established, the patients will be intubated with an uncuffed tracheal tube, and the patients will be allowed to breath spontaneously. The anesthetic gas (Halothane 2% in equal dose of O₂ and N₂O) will be delivered to patients by a mapelson system. Neostigmine-atropine (Rasht Pharmaceutical Manufactory) will not be injected in patients in spontaneous respiration group at the end of surgery. The patients will be extubated in a light plan of anesthesia (movement of head and hands).

Category

Treatment - Other

2

Description

In control ventilation group, after primary monitoring with ECG, SpO₂ and NIBP and after induction of anesthesia with intra-venous fentanyl 1microg/Kg (Rotex Medica Manufactory), thiopentone 4mg/Kg (Rotex Medica Manufactory), intra-venous atracurium(0.6 mg/kg) (Abooreyhan Manufactory) will be injected as muscle relaxant before intubation. After intubation with an uncuffed tracheal tube, the anesthetic gas (Halothane 2% in equal dose of O₂ and N₂O) will be delivered to patients by a circle system of anesthetic machine. The tidal volume will be set as 8-10 ml/kg and respiratory rate between 14-16 rate/minute. At the end of surgery, the muscle relaxant will be antagonized with neostigmine 50 microgram per kilogram-atropine 25 microgram per kilogram (Rasht Pharmaceutical Manufactory) in control ventilation group. The patients will be extubated in a light plan of anesthesia (movement of head and hands).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Medical Center Hospital

Full name of responsible person

Shahriari Ali, Associate Professor, Department of Anesthesiology

Street address

Pediatric Medical Center Hospital, Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, Vice Chancellor for research

Full name of responsible person

Dr Akbar Fotohi

Street address

Qods Street, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences, Vice Chancellor for research

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

Tehran University of Medical Sciences,

Full name of responsible person

Shahriari Ali

Position

Associate Professor, Department of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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