Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 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)
Phone
+98 21 3313 9215
Email address
ashahriari@tums.ac.ir

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-د

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
Street address
Roozbeh Hospital, South Kargar Street
City

Tehran
Postal code
Phone
+98 21 5560 9951
Fax
Email
Ashahriari@tums.ac.ir ;alibenmahdi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences,
Full name of responsible person
Shahriari Ali
Position
Anesthesiologist
Other areas of specialty/work
Street address
Roozbeh Hospital. South Kargar Street.
City
Tehran
Postal code
Phone
+98 21 5560 9951
Fax
Email
Ashahriari@tums.ac.ir ;alibenmahdi@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Roozbeh Hospital, South Kargar Street
City
Tehran
Postal code
Phone
+98 21 6694 8444
Fax
Email
Ashahriari@tums.ac.ir ; alibenmahdi@yahoo.com
Web page address

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