Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of different doses of propofol for laryngeal mask airway insertion in children

Protocol summary

Summary

In this double-blind randomized clinical trial, 120 patients from Tabriz children hospital with American society of Anesthesiologists (ASA) status I and II, weight less than 20 kg, undergoing inguinal hernia repair, chryptorchidism and so on, will be prospectively enrolled. The patients will be randomized in two 60-patients groups received intravenous midazolam (0.03mg/kg) as a premedication. Anesthesia induction will be with lidocaine1mg/kg, propofol 2.5mg/kg (group I) or lidocaine1mg/kg, propofol 3.5mg/kg (group II). LMA (laryngeal Mask Airway) size will be No 1 for children below 5 kg, No 1.5 for children between 5 -10 kg and No 2 for children between 10-20 kg. The LMA will be inserted with semi inflated cuff and 180 degree rotational method. The cuff will be filled with air after insertion. The ease of LMA insertion and its complication will be evaluated. The homodynamic changes, as well as possible complications will be determined during LMA insertion. If ventilation is not possible the LMA will be extracted and reinserted. In the case of patient movement propofol 2 mg/kg will be repeated. Cough, straining and time of LMA insertion will be recorded. The quality of air way will be graded: 1-There is air leakage with 20cmH2O of inspiratory pressure (normal capnography) 2-There is air leakage with abnormal capnography 3-ventilation is impossible. Apnea will be recorded after drug injection. Complications like cough, swallowing, limb movement during LMA insertion will be recorded. If LMA insertion will be unsuccessful after second try it will be failed and trachea will be intubated. Blood presure, heart rate, will be recorded before and after LMA insertion. The aim of this study will be finding the best dose of propofol for LMA insertion in children. The observer will be blind to the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101304041N3**
Registration date: **2011-04-16, 1390/01/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-04-16, 1390/01/27

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical sciences

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2011-04-18, 1390/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of different doses of propofol for laryngeal mask airway insertion in children

Public title
Propofol for Anesthesia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: children with ASA class I و II; candidated for lower abdominal surgeries, hernioraphy and so on; below 20 kg. Exclusion criteria: children with airway anomalies, hitory of upper respiratory infection in past 4 weeks.
Age
To **7 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research, Faculty of Medicine, Tabriz university of medical sciences
Street address
Tabriz University of Medical Sciences
City
Tabriz
Postal code
Approval date
2010-02-27, 1388/12/08
Ethics committee reference number
8812

Health conditions studied

1

Description of health condition studied
Pediatric Anesthesia
ICD-10 code
40.9
ICD-10 code description
Unilateral or unspecified inguinal hernia, without obstruction or gangrene

2

Description of health condition studied
pediatric anesthesia
ICD-10 code
K40.2
ICD-10 code description
Bilateral inguinal hernia, without obstruction or gangrene

3

Description of health condition studied
pediatric anesthesia
ICD-10 code
Q54
ICD-10 code description
Other congenital malformations of digestive system

Primary outcomes

1

Description
LMA insertion complication: cough, swallowing, larungospasm
Timepoint
once
Method of measurement
observation

Secondary outcomes

1

Description
Ease of LMA insertion
Timepoint
once, after insertion of LMA
Method of measurement
ease of ventilation (normal wave of capnography & no airway leakage after LMA insertion)

Intervention groups

1

Description
first group: propofol 2.5mg/kg for LMA insertion
Category
Prevention

2

Description
second group: propofol 3.5mg/kg for LMA insertion
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children Hospital
Full name of responsible person
Dr. Mahin Seyedhejazi
Street address
Tabriz Children Hospital
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Alireza Ostadrahimi
Street address
Golgasht st.
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz 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
Tabriz University of Medical Sciences
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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