

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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 pressure, 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

Name

Mahin Seyedhejazi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 2252

Email address

seidhejazi@tbzmed.ac.ir

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

Full name of responsible person

Dr.Mahin Seyedhejazi

Position

Associate Professor of Anesthesia

Other areas of specialty/work

Street address

Tabriz Children Hospital

City

Tabriz

Postal code

Phone

+98 41 1526 2250

Fax

Email

seidhejazi@yahoo.com , seidhejazi@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mahin Seyedhejazi

Position

Associate Professor of Anesthesia

Other areas of specialty/work

Street address

Tabriz Children Hospital

City

Tabriz

Postal code

Phone

+98 41 1526 2250

Fax

Email

seidhejazi@yahoo.com , seidhejazi@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Mahin Seyedhejazi

Position

Associate Professor of Anesthesia

Other areas of specialty/work

Street address

Tabriz Children Hospital

City

Tabriz

Postal code

Phone

+98 41 1526 2250

Fax

Email

seidhejazi@yahoo.com , seidhejazi@tbzmed.ac.ir

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