Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of propofol (4 mg/kg) and ketofol (2mg/kg propofol and 1mg/kg ketamine) for laryngeal mask airway insertion in children

Protocol summary

Summary

In this study we compare the effects of propofol and ketofol for LMA insertion in 60 children with ASA1 and 2 classes between 2-12 years old that candidate for surgery less than one hour. The patients are randomly divided in two groups : 30 patients in propofol group, receiving propofol 4 mg/kg and 30 patients in ketofol group, receiving propofol 2 mg/kg and ketamine 1 mg/kg. This study is a triple blind. Patients after entering operation room and preoxygenation with O2 100% for 2-3 minutes and standard monitoring (blood pressure, pulse oxymetry and ECG) are premedicate with midazolam 0.02 mg/kg and fentanyl 1 mcg/kg. Before and after anesthesia induction and after LMA insertion, vital signs (BP, HR, O2 saturation) are monitored. After injection of drugs, suitable LMA size are inserted (maximum effort for LMA insertion is 3 times). Time of loss of consciousness and eyelash reflex, severity of pain during injection, easiness and number of effort for LMA insertion, mouth opening for LMA insertion, swallow, cough, motion and laryngospasm are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502064041N10**
Registration date: **2015-04-07, 1394/01/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-04-07, 1394/01/18

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

seidhejazie@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

TABRIZ UNIVERSITY OF MEDICAL SCIENCES

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of propofol (4 mg/kg) and ketofol (2mg/kg propofol and 1mg/kg ketamine) for laryngeal mask airway insertion in children

Public title

Comparison of propofol (4 mg/kg) and ketofol (2mg/kg propofol and 1mg/kg ketamine) for laryngeal mask airway insertion in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 2-12 years old patients ; surgery less than one hour ; ASA 1 and 2 classes Exclusion criteria : risk of lung aspiration ; drugs allergy (propofol or ketamine) ; hard airway ; background neurological disease.

Age
From **2 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple 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 reaserch-Tabriz University of Medical Sciences
Street address
Tabriz-Golgasht Street-Medical University-Department of Vice Chancellor for reaserch
City
Tabriz
Postal code
Approval date
2014-04-28, 1393/02/08
Ethics committee reference number
9322

Health conditions studied

1

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

Primary outcomes

1

Description
blood pressure
Timepoint
before and after anesthesia induction and after LMA insertion
Method of measurement
manometer

2

Description
heart rate
Timepoint
before and after anesthesia induction and after LMA insertion
Method of measurement
by device measurement

3

Description
oxygen saturation
Timepoint
before and after anesthesia induction and after LMA insertion
Method of measurement
pulse oxymeter

Secondary outcomes

1

Description
pain intensity during drug injection-ease of laryngeal mask airway insertion -number of try foraryngeal mask airway insertion
Timepoint
after induction
Method of measurement
scale

Intervention groups

1

Description
In operation room 30 patients in propofol group receiving propofol 4 mg/kg
Category
Treatment - Drugs

2

Description
In operation room 30 patients in ketofol group receiving 2 mg/kg propofol and 1 mg/kg ketamine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children Hospital
Full name of responsible person
Seyed Hesam Fattahi
Street address
Tabriz - Sheshgilan Street - Children Hospital
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Hasan Soleimanpour
Street address
Golgasht Ave- Tabriz University of Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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 - Children Hospital
Full name of responsible person
Seyed Hesam Fattahi
Position
Medical student
Other areas of specialty/work
Street address
Tabriz - Sheshgelan street - Children Hospital
City
Tabriz
Postal code
Phone
+98 41 3477 3957
Fax
Email
hf_med87@yahoo.com
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
PROFESSOR
Other areas of specialty/work
Street address
Tabriz - Sheshgelan street - Tabriz Children Hospital
City
Tabriz
Postal code
Phone
+98 41 3477 3957
Fax
Email
seidhejazie@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mahin Seyedhejazi
Position
Professor
Other areas of specialty/work
Street address
Tabriz Children Hospital
City
Tabriz
Postal code
Phone
+98 41 3477 3957
Fax
Email
seidhejazie@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