Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Appropriate Time for Laryngeal Mask Airway Insertion in Patients Undergoing General Anesthesia

Protocol summary

Summary

In this prospective clinical trial 96 patients undergoing orthopedic surgeries will be studied in four groups . The aim of the study is to determine appropriate time for laryngeal mask airway insertion in patients undergoing general anesthesia .Inclusion Criteria : procedures less than 60 minutes ; patients between 16-65 year age ; American Society of Anesthesiologists class 1 & 2 . Exclusion Criteria : Difficult Airway ; Trauma in face and neck ; aspiration probability .According to the time of laryngeal mask insertion the patients will be included in four groups : group one 0-15 seconds , group two 16-30 seconds , group three 31-45 seconds and group four 46-60 seconds after completion of propofol injection. Induction of the anesthesia will be similar in all patients including propofol 2mg/kg , fentanyl 2 µg/kg and midazolam 0.03 mg/kg . Propofol will be injected during 30 seconds . Injection of the drugs and insertion of the LMA will be done by two anesthesiologists . Data will be recorded in a questionary form including : age , sex , ease of insertion , need for more drugs , blood pressure before the drugs and 1,3,5 minutes after LMA insertion , heart rate before the drugs and 1,3,5 minutes after LMA insertion , insertion time , gag reflex , cough , movements , laryngospasm , SaO2 before and after insertion , possibility of ventilation , sore throat after surgery , number of tries to insert LMA , mouth opening , and leak around the LMA cuff .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020226328N1**
Registration date: **2016-04-25, 1395/02/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-25, 1395/02/06

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

2015-12-22, 1394/10/01

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Appropriate Time for Laryngeal Mask Airway Insertion in Patients Undergoing General Anesthesia

Public title

Time for Laryngeal Mask Airway Insertion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : procedures less than 60 minutes ;

patients between 16-65 year age ; American Society of Anesthesiologists class 1 & 2 Exclusion criteria : Difficult Airway ; Trauma in face and neck ; aspiration probability

Age
From **16 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

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
Tabriz University of Medical Sciences

Street address
shohada Hospital ; Gholshahr Street ; Tabriz ; Iran

City
Tabriz

Postal code

Approval date
2015-12-07, 1394/09/16

Ethics committee reference number
TBZMED.REC.1394.830

Health conditions studied

1

Description of health condition studied
GENERAL ANESTHESIA

ICD-10 code
T88.4

ICD-10 code description
FAILED or DIFFICULT INTUBATION

Primary outcomes

1

Description
Appropriate Insertion Time

Timepoint
after intervention

Method of measurement
time

Secondary outcomes

1

Description
Hemodynamic Changes

Timepoint
after intervention

Method of measurement
monitoring

Intervention groups

1

Description
Four groups will be studied in regard of quality of laryngeal mask insertion . Quality of laryngeal mask insertion at different time interval after propofol injection will be studied . Laryngeal mask airway is a supraglottic airway device which is used to protect airway .Group one :Anesthesia will be induced with midazolam 0.03 mg/kg, fentany 2microgram/kg and propofol 2 mg/kg and while ventilating the patient , between 0 - 15 seconds after propofol injection the laryngeal mask will be inserted in a manner that tip of the index finger is at the back of the mask and the device is gently pushed down after the mouth is opened and when feeling a resistance the procedure is completed and the mask is fixed and the data about the quality of laryngeal mask insertion will be recorded .

Category
Other

2

Description
Group two : Anesthesia will be induced with midazolam 0.03 mg/kg, fentany 2microgram/kg and propofol 2 mg/kg and while ventilating the patient , between16 - 30 seconds after propofol injection the laryngeal mask will be inserted in a manner that tip of the index finger is at the back of the mask and the device is gently pushed down after the mouth is opened and when feeling a resistance the procedure is completed and the mask is fixed and the data about the quality of laryngeal mask insertion will be recorded .

Category
Treatment - Drugs

3

Description
Group three :Anesthesia will be induced with midazolam

0.03 mg/kg, fentany 2microgram/kg and propofol 2 mg/kg and while ventilating the patient , between 31 - 45 seconds after propofol injection the laryngeal mask will be inserted in a manner that tip of the index finger is at the back of the mask and the device is gently pushed down after the mouth is opened and when feeling a resistance the procedure is completed and the mask is fixed and the data about the quality of laryngeal mask insertion will be recorded .

Category

Treatment - Drugs

4

Description

Group four : Anesthesia will be induced with midazolam 0.03 mg/kg, fentany 2microgram/kg and propofol 2 mg/kg and while ventilating the patient , between46 - 60 seconds after propofol injection the laryngeal mask will be inserted in a manner that tip of the index finger is at the back of the mask and the device is gently pushed down after the mouth is opened and when feeling a resistance the procedure is completed and the mask is fixed and the data about the quality of laryngeal mask insertion will be recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Parish Masoud

Street address

Shohada Hospital , Gholshahr Street , Tabriz , Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

parish Masoud

Street address

Shohada Hospital

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

Full name of responsible person

Parish Masoud

Position

Anesthesiologist/Associate Professor

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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