

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the Success Rate of Airway Management by classic laryngeal mask airway(LMAc) and supraglottic gel mask(I-GEL) in elective orthopedic Surgeries

Protocol summary

Summary

The aim of this study is comparing the success rate of Laryngeal Mask Airway (LMA) and supraglottic gel airway (IGEL) in managing reliable airway in patients scheduled for elective orthopedic surgery under general anesthesia. Sixty 18-60 years old, ASA I,II patients scheduled for elective surgery, completed NPO time, with time of operation less than 1 hour and acceptable airway characteristics will be included. Morbid obese patients, history of GE reflux with any contraindication for general anesthesia and muscle relaxant injection will be excluded from the study. Patients will be divided in 2 groups. After standard monitoring, the same general anesthesia will be induced in all of them. Three minutes after injection of muscle relaxant LMA or IGEL will be inserted in each group based on the patients' weight. Successful insertion time is expressed from the time of reaching the instrument to lips until the first ventilation of patient with peak airway pressure equal to 15 cm H2O without any air leak (will be recorded in seconds). In the situations of failure in the first attempt, the instrument will be removed and try again, this stages will be done until 3 times. The main outcomes of the study are the number of attempts and the time spent until favorable ventilation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307284969N7**

Registration date: **2014-05-11, 1393/02/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-11, 1393/02/21

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Tehran University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Firoozgar Hospital- Iran University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Success Rate of Airway Management by classic laryngeal mask airway(LMAc) and supraglottic gel mask(I-GEL) in elective orthopedic Surgeries

Public title

Airway Management by classic laryngeal mask airway(LMAc) or supraglottic gel mask(I-GEL)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 60 years, ASA I,II patients scheduled for elective surgery, complete NPO time,time of operation less than 1 hour, airway characteristics: TMD>6 cm, mallampati I,II, mouth opening>2 finger width. Exclusion criteria: NPO time<8 hours, morbid obesity, BMI>30, history of GE reflux, no contraindication for general anesthesia and muscle relaxant injection

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

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 Iran University of Medical Sciences

Street address

Next to Milad tower, Hemmat highway

City

Tehran

Postal code

Approval date

2014-04-26, 1393/02/06

Ethics committee reference number

374/105/93/5

Health conditions studied

1

Description of health condition studied

maintain reliable airway with different instruments in leg fractures

ICD-10 code

s82.9

ICD-10 code description

Fracture of lower leg, part unspecified

Primary outcomes

1

Description

success in patient ventilation without air leak

Timepoint

after instrument insertion

Method of measurement

Questionnaire

2

Description

Time spent to maintain reliable airway

Timepoint

after instrument insertion

Method of measurement

Questionnaire

Secondary outcomes

1

Description

post surgical sore throat

Timepoint

after the operation in recovery room

Method of measurement

recording by questionnaire

2

Description

hoarseness

Timepoint

after the operation in recovery room

Method of measurement

recording by questionnaire

Intervention groups

1

Description

Insertion of supraglottic gel airway (IGEL) for maintaining airway(intervention2) made by Intersurgical company, united kingdom

Category

Treatment - Other

2

Description

insertion of Laryngeal Mask Airway for maintaining airway(intervention1) made by Huiyan company, china

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Foroozgar Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research,Iran University of Medical Sciences

Full name of responsible person

Dr. Morteza Naserbakht

Street address

Iran University of Medical Sciences- Hemmat Highway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor of research,Iran 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

Iran University of Medical Sciences- Firoozgar Hospital

Full name of responsible person

Alireza Pournajafian

Position

Assistant professor of Anesthesia

Other areas of specialty/work

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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