

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparing the effectiveness of the classic laryngeal mask (LMA) with the supralaryngeal (SLIPA) in general anesthesia

Protocol summary

Summary

This study is a single-blind randomized clinical trial on 320 patients at the Medical University of Arak, that have been randomly selected. All patients needed general anesthesia for general, orthopedic, urologic and gynecological surgery. IV LINE embedded and standard monitoring (blood pressure, heart rate and pulseoximetry) was performed for all patients. All patients got similar drugs for general anesthesia. Insertion of LMA or SLIPA was performed randomly, 2 min after induction of anesthesia Laryngeal mask insertion was performed by an anesthesiologist and water-soluble gel used for lubrication. How to insertion a laryngeal mask and insertion time is recorded. Mechanical ventilation performed with 8 ml / kg volume and 12b/min and the fresh gas flow rate 3 L / min. Oxygen saturation is recorded every 5 minutes until 15 minutes after anesthesia. Air insufflations into the stomach was monitored by listening with stethoscope and recorded on three times (Immediately after insertion the mask, after 15 minutes and at the end of surgery). Laryngeal mask is removed when the patient is breathing spontaneously, tidal volume 8 ml / kg and the verbal responses to simple stimuli. Removing the mask could be easy or difficult that was recorded. The patient was asked for sore throat (VAS) 30 minutes after removal of the mask. Bleeding in the throat or on the mask was recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201072080N12**
Registration date: **2012-03-15, 1390/12/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-15, 1390/12/25

Registrant information

Name

Afsaneh Norouzi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

norouzi.a@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Department of education and research of Arak university of medical sciences

Expected recruitment start date

2010-04-17, 1389/01/28

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of the classic laryngeal mask (LMA) with the supralaryngeal (SLIPA) in general anesthesia

Public title

Comparing the effectiveness of the classic laryngeal mask (LMA) with the supralaryngeal (SLIPA) in general anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing general, orthopedics, urologic and gynecologic surgery who have a need for general anesthesia; supine position; patients aged 15-70 years; ASA I - II; BMI less than 35; practice time less than one hour; preoperative fasting for at least 6 hours. Exclusion criteria: sore throat; pregnancy; history of reflux.

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **320**

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

Arak university of medical sciences

Street address

Alamol hoda street

City

Arak

Postal code

Approval date

2010-01-27, 1388/11/07

Ethics committee reference number

88-73-2

Health conditions studied

1

Description of health condition studied

Urologic surgery

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

2

Description of health condition studied

general surgery

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

3

Description of health condition studied

orthopedic surgery

ICD-10 code

M02

ICD-10 code description

Reactive arthropathies

4

Description of health condition studied

gynecologic surgery

ICD-10 code

O02

ICD-10 code description

Other abnormal products of conception

5

Description of health condition studied

general surgery

ICD-10 code

K60

ICD-10 code description

Fissure and fistula of anal and rectal regions

6

Description of health condition studied

general surgery

ICD-10 code

K61

ICD-10 code description

Abscess of anal and rectal regions

7

Description of health condition studied

general surgery

ICD-10 code

I84

ICD-10 code description

Haemorrhoids

Primary outcomes

1

Description

How to insertion of laryngeal mask

Timepoint

Insertion of laryngeal mask

Method of measurement

Observation

2

Description

Insertion time

Timepoint

Immediately after insertion of laryngeal mask

Method of measurement

Observation

3

Description

How to remove the laryngeal mask

Timepoint

After removing the mask

Method of measurement

Observation

Secondary outcomes

1

Description

Sorethroat

Timepoint

30 minutes after removing the mask

Method of measurement

VAS and observation

2

Description

Blood on laryngeal mask

Timepoint

After removing the mask

Method of measurement

Observation

3

Description

Gastric insufflation

Timepoint

After insertion of laryngeal mask

Method of measurement

Clinical examination

Intervention groups

1

Description

In the first 2 minutes after induction of anesthesia put LMAc and how to insert a laryngeal mask, insertion time by seconds, arterial blood saturation, the air entering the stomach , easy or difficult to remove the mask and sore throat and blood on the mask were recorded

Category

Other

2

Description

In the first 2 minutes after induction of anesthesia put SLIPA and how to insert a laryngeal mask, insertion time by seconds, arterial blood saturation, the air entering the stomach , easy or difficult to remove the mask and sore throat and blood on the mask were recorded

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valieasr hospital

Full name of responsible person

Dr. Afsaneh Norouzi

Street address

City

Arak

2

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr. Afsaneh Norouzi

Street address

City

Arak

3

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr. Afsaneh Norouzi

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak university of medical sciences

Full name of responsible person

Dr. Changizi Ashtiyani

Street address

Alamol hoda street

City

Arak

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Arak 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
Arak university of medical sciences

Full name of responsible person
Dr.Afsaneh Norouzi

Position
Asistant professor, Anesthesiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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