

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Laryngeal mask airway (LMA) compared to endotracheal tube (ETT) for mild asthmatic patients undergoing emergent surgery regarding airway pressure

Protocol summary

Summary

Main goal of the study is to assess airway pressure in asthmatic patients anesthetized by LMA or ETT (during first 20 minutes after induction of anesthesia and afterwards). Design: Twenty patients will be enrolled in each group (L who received LMA or T who received ETT). Method: They both receive same protocol for induction (propofol, cisatracurium, fentanyl, midazolam) and maintenance. Outcomes: Airway pressure at each breath (continuously during first 20 minutes and every 5 minutes afterwards) and arterial saturation will be assessed and out of predefined values will be recorded and treated accordingly. Patients will be extubated in a fully awake status. Cough, desaturation, nausea, vomiting, dyspnea and wheeze will be evaluated in recovery.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201511223436N5**

Registration date: **2015-12-23, 1394/10/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-23, 1394/10/02

Registrant information

Name

Babak Gharaei

Name of organization / entity

Labbafijejad Hospital, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Laryngeal mask airway (LMA) compared to endotracheal tube (ETT) for mild asthmatic patients undergoing emergent surgery regarding airway pressure

Public title

General anesthesia in asthmatic patients, airway management

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion: aged 16-59. no cardiac problem. no medical problem except asthma. asthma can be active however should be categorized as mild with no respiratory distress or desaturation less than 90%. Exclusion: surgery duration more than 2 hours. Changing head position more than three times in the surgery.

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Daneshjoo Sq, Shahid Beheshti University of Medical Sciences

City

Tehran

Postal code**Approval date**

2015-08-25, 1394/06/03

Ethics committee reference number

IR.SBMU.SM.REC.1394.18

Health conditions studied**1****Description of health condition studied**

Asthma

ICD-10 code

J45-2, J45

ICD-10 code description

Mild intermittent and persistent asthma

Primary outcomes**1****Description**

Arterial oxygen desaturation

Timepoint

Continuous pulse measurement during anesthesia and recovery

Method of measurement

arteril oxygen desaturation to less than 90% for longer than one minute

2**Description**

Airway pressure more than 30 with LMA or 50 by ETT

Timepoint

continuous- breath by breath in the first 20 minutes and every 5 minutes afterwards

Method of measurement

Airway pressure in CmH2o by Anesthesia machine

Secondary outcomes**1****Description**

Nausea and vomiting

Timepoint

Every 5 minutes in recovery

Method of measurement

Asking from the patient

2**Description**

Dyspnea

Timepoint

Every 5 minutes in recovery after being fully awake

Method of measurement

asking from the patient

3**Description**

Respiratory wheeze

Timepoint

Every 30 minutes in recovery

Method of measurement

Auscultation for wheeze (inspiratory -expiratory- mild, moderate or severe)

Intervention groups**1****Description**

Intervention in T group: After induction and in deep state of anesthesia with proper muscle relaxation, appropriate size ETT (SUPA Co. Tehran, Iran) is placed for the patient.

Category

Prevention

2**Description**

Intervrntion in L group: After induction and in deep state

of anesthesia with proper muscle relaxation, appropriate size LMA (Well Lead, China) is placed for the patient.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejad Hospital

Full name of responsible person

Babak Gharaei

Street address

9th Boostan, Paydar fard, Pasdaran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Babak gharaei

Street address

Labbafinejad , 9th Boostan, Pasdaran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

Medical School, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Babak Gharaei

Position

Associate Professor

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