

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative evaluation of Laryngeal mask insertion with conventional tracheal intubation on cardiovascular response during general anesthesia

Protocol summary

Summary

The aim of this study is to determine the cardiovascular response to Laryngeal mask insertion versus laryngoscopy and tracheal intubation. In this double blind randomized clinical trial 82 male or female with 20 to 45 years old that are scheduled for elective open limb surgery, appendectomy and inguinal herniorrhaphy at operating room in the Shahroud's Imam Hossein hospital. After obtaining justification and consent, participants will be placed in LMA(intervention) or tracheal intubation(control) group. Management of anesthesia in both groups is identical (fentanyl premedication, induction with thiopental, muscle relaxation with atracurium and maintenance of anesthesia with isoflurane with equal proportions of oxygen and Nitrous oxide). After induction of anesthesia and muscle relaxation in intervention group, size 3 of unique single use LMA for women and size 4 for men, and in control group Tracheal tube with size 7.5 for women and 8.0 for men will be inserted. Management of airway control in all participants will be done with standard technique and by one anesthetist. Measurable outcomes are pulse rate, systolic and diastolic blood pressure. A trained nurse charts these variables from cardiovascular monitor just before anesthesia, after induction and muscle relaxation, during airway control and then every 5 minutes during operation. A screen separates sampler from anesthetist so he/she can't see patient's airway management.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052712123N6**

Registration date: **2016-06-18, 1395/03/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

Name

Javad Nourian

Name of organization / entity

Imam Hossein Hospital, Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 27 3334 2001

Email address

javadnourian@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research, Shahroud University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of Laryngeal mask insertion with conventional tracheal intubation on cardiovascular response during general anesthesia

Public title

Comparison of cardiovascular response to laryngeal mask airway versus tracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male or female; 20-45 years old; ASA class 1 or 2 (anesthesia risk); elective limbs open surgery; hernia; appendectomy. Exclusion criteria: Patient's refusal; hypertension; antihypertensive medication; opiate and analgesic drug abuse; every anesthesia or surgical complication.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

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

Double 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, Deputy of research, Shahroud University of Medical Sciences

Street address

Deputy of research, Shahroud University of Medical Sciences, 7th of Tir square

City

Shahroud

Postal code

3614773955

Approval date

2015-01-21, 1393/11/01

Ethics committee reference number

930.31

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

Humerus fracture

ICD-10 code

S42.3, S42

ICD-10 code description

Fracture of shaft of humerus, Fracture of lower end of humerus

2**Description of health condition studied**

Fracture of both ulna and radius

ICD-10 code

S52.6, S52

ICD-10 code description

Fracture of lower end of both ulna and radius, Multiple fractures of forearm, Fracture of other parts of forearm

3**Description of health condition studied**

Fracture at wrist and hand level

ICD-10 code

S62.0, S62

ICD-10 code description

Fracture of navicular [scaphoid] bone of hand, Fracture of other carpal bone(s), Fracture of first metacarpal bone, Fracture of other metacarpal bone, Multiple fractures of metacarpal bones, Fracture of thumb, Fracture of other finger, Multiple fractures

4**Description of health condition studied**

Leg fracture

ICD-10 code

S82.0, S82

ICD-10 code description

Fracture of lower leg, including ankle

5**Description of health condition studied**

Appendectomy

ICD-10 code

K35.3

ICD-10 code description

Acute appendicitis

6**Description of health condition studied**

Inguinal hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

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

Systolic blood pressure

Timepoint

before anesthesia, after induction, during airway control(laryngoscopy and intubation in control group and LMA insertion in intervention group), every five minutes during operation

Method of measurement

mmHg by Novin saadat's monitoring

2

Description

Pulse rate

Timepoint

before anesthesia, after induction, during airway control(laryngoscopy and intubation in control group and LMA insertion in intervention group), every five minutes during operation

Method of measurement

Beat per minutes by Novin saadat's monitoring

3

Description

Diastolic blood pressure

Timepoint

before anesthesia, after induction, during airway control(laryngoscopy and intubation in control group and LMA insertion in intervention group), every five minutes during operation

Method of measurement

mmHg by Novin saadat's monitoring

Secondary outcomes

1

Description

Postoperative sore throat

Timepoint

At the end of recovery and 4 hours after in ward

Method of measurement

0-3 scoring system 0-none 1- mild 2-moderate 3- severe

Intervention groups

1

Description

Intervention group: After induction of anesthesia and muscle relaxation size 3 unique singe use LMA for women and size 4 for men will be inserted cuff pressure adjusts by cuff pressure manometer.

Category

Treatment - Devices

2

Description

Control group: After induction of anesthesia and muscle relaxation laryngoscopy and intubation with size 7.5 cuffed tracheal tube for women and size 8.0 for men will be done and cuff pressure adjusts by cuff pressure manometer

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room, Imam hossein hospital

Full name of responsible person

Javad Nourian MD

Street address

Operating room, Imam Hossein Hospital, End of Ayatollah Towhidi avenue

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research, Shahroud University of Medical Sciences

Full name of responsible person

Mohammad hasan Emamian

Street address

Deputy of research, Shahroud University of Medical Sciences, 7th of Tir square

City

Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of research, Shahroud 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

Imam Hossein Hospital, Shahroud University of Medical Sciences, Shahroud, Iran

Full name of responsible person

Javad Nourian MD

Position

Assistant professor of anesthesiology, department of anesthesia and intensive care

Other areas of specialty/work

Street address

Operating room Imam Hossein Hospital, End of Towhidi avenue Shahroud

City

Shahroud

Postal code

3616911151

Phone

+98 23 3234 2001

Fax

+98 23 3233 3902

Email

javadnourian@shmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Hossein Hospital, Shahroud University of Medical Sciences, Shahroud, Iran

Full name of responsible person

Javad Nourian MD

Position

Assistant professor of anesthesiology, department of anesthesia and intensive care

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+98 23 3233 3902

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Person responsible for updating data

Contact

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Fax

+98 23 3233 3902

Email

javadnourian@shmu.ac.ir

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