

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of endotracheal airway intubation and laryngeal mask (LMA) methods on respiratory parameters in patients undergoing elective orthopedic surgery

Protocol summary

Study aim

Reduction of respiratory complications in patients undergoing orthopedic surgery

Design

Clinical trial with two groups of 48 people with parallel groups (establishment of airway with Endotracheal tube and establishment of airway with laryngeal mask, blind bilateral, randomized using Random allocation software

Settings and conduct

The study will be performed at Hormozgan University of Medical Sciences. All patients will be admitted to the orthopedic ward before surgery will be reserved for all patients 2 units of blood. Preliminary tests will be requested for patients. All patients will receive 40mg of pantoprazole and 1 mg of lorazepam orally. In the operating room, all patients are monitored by EKG and pulse oximetry and blood pressure control. Induction of anesthesia will be considered the same for all patients (propofol 2 mg / kg and atracurium 0.5 mg / kg). Then patients are placed in two groups : group 1 for endotracheal intubation (No. 7.5 for females and No. 8 for males) 3 minutes after injection of atracurium and ventilation with 100% oxygen and for group 2 of laryngeal mask is used with appropriate size based on weight of the patient . The duration of surgery and hemodynamic parameters in each group are recorded after airway establishment and at 1,3,5,10,15 minutes after intubation.

Participants/Inclusion and exclusion criteria

96 patients of both sexes aged 18-70 years with ASA I, II candidates for elective orthopedic surgery No entry conditions: History of COPD, Asthma, ILD, and Pulmonary fibrosis or active lung infection Ejection fraction (EF) less than 40%, BMI > 35 kg / m², Emergency surgery Airway malformation

Intervention groups

The first group is a candidate for airway intubation The

second group nominates a laryngeal mask

Main outcome variables

Arterial Oxygen Saturation Percentage; End-tidal carbon dioxide; Peak Airway Pressure; Plateau Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220612055153N1**

Registration date: **2022-06-26, 1401/04/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-26, 1401/04/05**

Update count: **0**

Registration date

2022-06-26, 1401/04/05

Registrant information

Name

Majid Vatankhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 7001

Email address

m.vatankhah@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of endotracheal airway intubation and laryngeal mask (LMA) methods on respiratory parameters in patients undergoing elective orthopedic surgery

Public title
Evaluation of the effect of endotracheal intubation and laryngeal mask on respiratory parameters

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 70 years ASA I, II candidate for elective orthopedic surgery under general anesthesia
Exclusion criteria:
History of COPD, asthma, ILD, and pulmonary fibrosis with active lung infection EF fraction (less than 40%) BMI > 35 kg / m2 Emergency surgery Airway malformation

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to eliminate the bias caused by the patient's awareness or anesthesia assistant and evaluator of the results and its possible effect on the research result, the study is performed as a two-way blind and a random number table.

Blinding (investigator's opinion)
Double blinded

Blinding description
Random allocation was performed based on Random allocation software and based on that, the even numbers of the table were considered for airway intubation and the odd numbers of the table were considered for laryngeal mask placement. The numbers were placed in sealed envelopes and by someone other than the procedure Returned and based on that the airway was managed by an anesthesia assistant.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Hormozgan University Of Medical Sciences

Street address

Jomhuri Blvd, Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Approval date

2021-12-13, 1400/09/22

Ethics committee reference number

IR.HUMS.REC.1400.344

Health conditions studied

1

Description of health condition studied

Orthopedic patients

ICD-10 code

Z47

ICD-10 code description

Orthopedic aftercare

Primary outcomes

1

Description

Investigation of respiratory parameters

Timepoint

Evaluation of respiratory parameters at 1, 3, 5, 10 and 15 minutes after airway establishment

Method of measurement

Measurement of arterial oxygen saturation percentage by pulse oximetry device and End-tidal carbon dioxide(Etco2) via capnograph

Secondary outcomes

1

Description

Respiratory complications during surgery

Timepoint

Measurement of respiratory parameters such as blood oxygen saturation percentage (spo2) and end-tidal carbon dioxide (Etco2) at 1, 3, 5, 10 and 15 minutes after establishing airway

Method of measurement

Intervention groups

1

Description

Intervention group: Establishment of airway through endotracheal tube

Category

Treatment - Devices

2

Description

Control group: Establishment of airway through laryngeal mask (LMA)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Majid Vatankhah

Street address

Jomhuri Blvd., Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 5009

Email

m.vatankhah@hums.ac.ir

2

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Majid Vatankhah

Street address

Jomhuri Blvd., Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 5009

Email

m.vatankhah@hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Timur Aghamlaei

Street address

Deputy of research and technology, East Side, Bandar Abbas Hospital, Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 71 3333 5794

Email

taghamolaei@hums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Majid Vatankhah

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Jomhuri BLV

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 5009

Email

m.vatankhah@hums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Majid Vatankhah

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Jomhuri Blvd, Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 5009

Email

m.vatankhah@hums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Majid Vatankhah

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Jomhuri Blvd, Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 5009

Email

m.vatankhah@hums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared

When the data will become available and for how long

After confirming the publication of the article

To whom data/document is available

All Researchers

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Dr.Majid Vatankhah through
email:m.vatankhah@hums.ac.ir

What processes are involved for a request to access data/document

After the investigation of researcher request and presentation of required documents will be accessible.

Comments