

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of hemodynamic changes in the use of two methods of trapezius compression and mandibular lifting to determine the right time to insert a laryngeal mask in patients under general anesthesia with sodium thiopental

Protocol summary

Study aim

1. Comparison of average systolic and diastolic blood pressure of patients before and 2 minutes after induction and after LMA insertion 2. Comparison of the average heart rate of patients 2 minutes after induction and after LMA insertion in each of the two methods 3. Comparison of the average SpO2 of patients 2 minutes after induction and after LMA placement in two methods 4. Comparison of the average LMA insertion time in two methods 5. Comparison of hemodynamic changes compared to the base level

Design

A clinical trial with two intervention groups of 69 patients each, double-blind, simple randomization by block method and matching

Settings and conduct

The place of study is the operating room of Imam Reza Hospital, Birjand city After obtaining informed consent and recording information, the patients will be randomly divided into two groups A (squeezing the trapezius muscle) and B (pulling up the lower jaw) and induction of anesthesia with midazolam, fentanyl and sodium thiopental drugs as an anesthetic without blocking drugs. It is done neuromuscularly Then, one minute after the induction of anesthesia, one of the trapezius muscle squeezing maneuvers or the mandibular lifting maneuver is performed every 20 seconds until the

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-70 years old, having informed consent Exit criteria for emergency, suffering from uncontrolled systemic disease, hemodynamic instability, pregnancy, blood pressure, drug abuse, malampathy 2 or higher, body mass index greater than 30, neck movement disorder, difficulties in opening the mouth and the inability to ventilate after using a laryngeal mask.

Intervention groups

Group A - trapezius muscle squeezing maneuver Group B - lower jaw lifting maneuver(common method)

Main outcome variables

Systolic, diastolic and average blood pressure, heart rate, arterial blood oxygen saturation percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221115056503N1**

Registration date: **2023-02-01, 1401/11/12**

Registration timing: **retrospective**

Last update: **2023-02-01, 1401/11/12**

Update count: **0**

Registration date

2023-02-01, 1401/11/12

Registrant information

Name

Hosein Abdollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3220 4024

Email address

hoseinabdollahi@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic changes in the use of two methods of trapezius compression and mandibular lifting to determine the right time to insert a laryngeal mask in patients under general anesthesia with sodium thiopental

Public title

Comparison of hemodynamic changes in the use of two methods of trapezius compression and mandibular lifting to determine the right time to insert a laryngeal mask in patients under general anesthesia with sodium thiopental

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 70 years Having informed consent to enter the study Patient in need of general anesthesia

Exclusion criteria:

Emergency Body mass index is greter than 30
Uncontrolled systemic disease Hemodynamic instability
Uncontrolled Hypertention Pregnancy Substance abuse
mallampathy more than 2 Limitation of neck extension
Difficulties in opening the mouth and impossibility of
ventilation fter laryngeal msk application

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **138****Randomization (investigator's opinion)**

Randomized

Randomization description

After determining the eligible people to enter the study for random assignment between two groups (group A: squeezing the trapezius muscle and group B: raising the lower jaw), a random block method with concealment will be used. There are four (AABB, BBAA, ABAB, BABA, ABBA, BAAB) and each block will be randomly selected. RANDBETWEEN command (random selection with repetition) was used in Excel software to generate a random sequence (selection of blocks). Closed opaque envelopes will be used for concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients do not know how to be placed in groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Birjand University of Medical Sciences

Street address

No. 9, Allay No. 13, Adel St

City

Birjand

Province

South Khorasan

Postal code

9717677715

Approval date

2022-11-09, 1401/08/18

Ethics committee reference number

IR.BUMS.REC.1401.302

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

Candidates for surgery under general anesthesia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hemodynamic changes and LMA operation time in patients under general anesthesia

Timepoint

Before induction, every twenty seconds after the first minute and two minutes after induction

Method of measurement

Patient monitoring in the operating room

Secondary outcomes

empty

Intervention groups

1

Description

1- Pulling the lower jaw up (common method): placing the fingers in the angle of the mandible on both sides and pulling the lower jaw upwards and checking the patient's movement response

Category

Treatment - Other

2

Description

Intervention group2: Squeezing the trapezius muscle on both sides at a distance of two to three centimeters from the root of the neck between the first and second fingers of the hand and examining the patient's motor response.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Birjand city

Full name of responsible person

Hosein Abdollahi

Street address

Taleghani Street, Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammd hosein Nmaei

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

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

100

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

Birjand University of Medical Sciences

Full name of responsible person

Hosein Abdollahi

Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no need to share non-identifiable personal data of the participants, and there is no scientific justification for publishing this data

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available