

# 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

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

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**Target 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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**Email**

hoseinabdollahi@bums.ac.ir

## 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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No 9 , allay No 13 , Adl st

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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**

Anesthesiology

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## Person responsible for scientific inquiries

#### Contact

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**Position**

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

Birjand University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**City**

Birjnd

**Province**

South Khorasan

**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