

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Endotracheal intubation with laryngeal mask airway and bougie versus video laryngoscope in patients with difficult airway

#### Protocol summary

##### Summary

Objectives: Selecting the appropriate method of intubation in patients with difficult airway, is an important challenge for anesthesiologists because repeated attempts of intubation increase complications such as hypoxia, hemodynamic abnormalities, aspiration and damage to the airway. The aim of this study is to compare the endotracheal intubation with laryngeal mask airway and bougie versus video laryngoscope in patients with difficult airway. Design: Block randomization, without placebo, double center, trial phase 2, including 90 patients who are candidate for elective surgeries. Setting and conduct: Fentanyl, 1 µg/kg, IV injection to induce anesthesia. Propofol, 2 mg/kg, IV injection to induce anesthesia. Participants including major eligibility criteria: All patients who are candidate for elective surgeries. Intervention: Endotracheal intubation with video laryngoscope Endotracheal intubation with laryngeal mask airway and bougie Main outcome measures: Ease of intubation, Duration of intubation, Systolic blood pressure, Diastolic blood pressure, O2 saturation, Heart rate.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015102214056N6**

Registration date: **2015-10-26, 1394/08/04**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-10-26, 1394/08/04

##### Registrant information

**Name**

Hesameddin Modir

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 86 3313 9680

**Email address**

he\_modir@arakmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Arak University of Medical Sciences, Vice Chancellor for Research

**Expected recruitment start date**

2015-11-22, 1394/09/01

**Expected recruitment end date**

2016-03-20, 1395/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Endotracheal intubation with laryngeal mask airway and bougie versus video laryngoscope in patients with difficult airway

**Public title**

Breathing intubation with two different methods in patients with difficult intubation

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: ASA class I-II; Age between 18-65 years old; Mallampati class III-IV; Negative upper lip bite test; Patients satisfaction; Not pregnant; No history of cardiovascular diseases (Arrhythmia, ischemia, and heart block); No history of coagulopathies; Not taking opioids.

Exclusion criteria: Insufficient ventilation or lack of ventilation in time of induction.

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **90**

### 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

Ethics committee of Arak University of Medical Sciences

##### Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

##### City

Arak

##### Postal code

IR.ARAKMU.REC.1394.4

##### Approval date

2015-09-23, 1394/07/01

##### Ethics committee reference number

IR.ARAKMU.REC.1394.43

## Health conditions studied

### 1

#### Description of health condition studied

Difficult intubation

#### ICD-10 code

T88.4

#### ICD-10 code description

Failed or difficult intubation

## Primary outcomes

### 1

#### Description

Ease of intubation

#### Timepoint

After intubation

#### Method of measurement

Qualitative score

### 2

#### Description

The duration of intubation

#### Timepoint

After intubation

#### Method of measurement

Quantitative

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention 1. Endotracheal intubation with video laryngoscope.

#### Category

Other

### 2

#### Description

Intervention 2. Endotracheal intubation with laryngeal mask airway and bougie.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir kabir hospital

##### Full name of responsible person

Dr Hesameddin Modir

##### Street address

Amir kabir hospital. Parastar square. Rah-Ahan street. Arak. Iran

##### City

Arak

### 2

#### Recruitment center

##### Name of recruitment center

Vali asr hospital

**Full name of responsible person**

Dr Hesameddin Modir

**Street address**

Vali asr hospital. Vali asr square. Arak. Iran

**City**

Arak

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences, Vice Chancellor for Research

**Full name of responsible person**

Dr Ali Asghar Yaghoobi

**Street address**

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

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Arak

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

Yes

**Title of funding source**

Arak University of Medical Sciences, Vice Chancellor for Research

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Hesameddin Modir

**Position**

Anesthesiologist

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**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*