

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

He_modir@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Hesameddin Modir

Position

Anesthesiologist

Other areas of specialty/work**Street address**

Arak University of Medical Sciences. Basij Square.

Sardasht. Arak. Iran

City

Arak

Postal code**Phone**

+98 86 3417 3641

Fax**Email**

He_modir@yahoo.com

Web page address**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

City

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

Other areas of specialty/work**Street address**

Arak University of Medical Sciences. Basij Square.

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Arak

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+98 86 3417 3641

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

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+98 86 3417 3641

Fax**Email**

He_modir@yahoo.com

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