Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
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2

Recruitment center

Name of recruitment center
Vali asr hospital

Full name of responsible person
Dr Hesameddin Modir
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Vali asr hospital. Vali asr square. Arak. Iran
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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
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Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran
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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
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
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Person responsible for updating data

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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