

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the success rate of intubation using bougie and stylet in patients under general anesthesia

Protocol summary

Study aim

The success rate of intubation is compared using bougie and stylet guide in patients under general anesthesia. If the results of the study show the superiority of one method over the other (ease of intubation and absence of complications), that method can be used in cases of hard intubation.

Design

Clinical trial with two intervention groups, parallel groups, double blind, randomized with <https://www.sealedenvelope.com/> site, without phase, each group consisting of 67 people

Settings and conduct

Patients are randomly assigned into two equal groups with block randomization. Intubation in the first group is done by the tracheal tube and the stylet guide inside it, and in the second group, we transfer the tracheal tube into the trachea with the guide of a bougie. In each of the two methods, the required time for successful intubation in each patient will be recorded by a stopwatch. The patients and the investigator responsible for collecting the data are blinded to the randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA Class 1 and 2 Between 18 and 65 years old Mallampati Class 3 and 4 Mandibular protrusion test class B & C Patient satisfaction Absence Pregnancy No history of cardiovascular disease Absence of coagulation disorders Nondrug use Exclusion criteria: Insufficient or no ventilation during induction Unsuccessful intubation

Intervention groups

The first intervention group: Intubation is performed using a tracheal tube with a stylet guide at an angle of 25 to 35 degrees. The second intervention group: intubation is performed using a bougie. First, we will place a bougie into the larynx with a laryngoscope, and then we will move the tracheal tube into the trachea on the bougie.

Main outcome variables

Comparison of the required time for successful intubation and the rate of ease of endotracheal intubation in each group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230508058115N1**

Registration date: **2023-08-19, 1402/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-19, 1402/05/28**

Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Elham Sedghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the success rate of intubation using bougie and stylet in patients under general anesthesia

Public title
Comparison of the success rate of intubation using bougie and stylet

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
ASA class 1 & 2 Age between 18- 65 years Mallampati class 3 & 4 Mandibular protrusion test Class B & C Patient satisfaction Not pregnant No history of cardiovascular disease (Cardiac arrhythmia, ischemia, heart block) Absence of coagulopathy No substance abuse
Exclusion criteria:
Insufficient or no ventilation during induction failed intubation (if intubation is not done after three attempts, intubation is done using a glide scope or LMA and they are excluded from the study.)

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **134**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into two equal groups with block randomization in blocks of 4. Random sequences are performed using the online application on the <https://www.sealedenvelope.com/> site. Random chain hiding is done using matte envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and the investigator responsible for collecting data are blind.

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

Faculty of medicine, Arak University of Medical Sciences, Great Prophet University Complex, Basij Square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.ARAKMU.REC.1401.344

Health conditions studied

1

Description of health condition studied

Intubation with stylet

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

2

Description of health condition studied

Intubation with bougie

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

Primary outcomes

1

Description

The time required for successful intubation with a stylet guide

Timepoint

Measuring the time required for successful intubation of a patient under general anesthesia

Method of measurement

Stopwatch

2

Description

The time required for successful intubation with a bougie

Timepoint

Measuring the time required for successful intubation of

a patient under general anesthesia

Method of measurement

Stopwatch

Secondary outcomes

1

Description

Determining the ease of intubation with a stylet guide

Timepoint

Determining the ease of intubation while doing it

Method of measurement

Easy intubation means successful intubation on the first attempt in less than 15 seconds, relatively difficult intubation means successful intubation in 15-30 seconds, and difficult intubation means successful intubation with more than one attempt. (Successful intubation on the second attempt) and failure to perform intubation is called inability to intubate using any of the studied methods.

2

Description

Determining the ease of intubation with a bougie

Timepoint

Determining the ease of intubation while doing it

Method of measurement

Easy intubation means successful intubation on the first attempt in less than 15 seconds, relatively difficult intubation means successful intubation in 15-30 seconds, and difficult intubation means successful intubation with more than one attempt. (Successful intubation on the second attempt) and failure to perform intubation is called inability to intubate using any of the studied methods.

Intervention groups

1

Description

first Intervention group: intubation using a tracheal tube with a stylet guide and recording the time and the number of attempts required for successful intubation.

Category

Treatment - Devices

2

Description

second Intervention group: intubation using a tracheal tube and a bougie and recording the time and the number of attempts required for successful intubation.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Hesameddin Modir

Street address

Valiasr Hospital, Valiasr Square, Imam Khomeini Street, Arak

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5755838149

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpou

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Research and Technology Vice-Chancellor, Great Prophet University Complex, Arak University of Medical Sciences, Arak

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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

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

Arak University of Medical Sciences

Full name of responsible person

Hesameddin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

Hesameddin Modir

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

protecting patient privacy

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available