

# 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)

##### Phone

+98 86 3417 3526

##### Email address

esedghi98@gmail.com

##### 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

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

5755838149

##### **Phone**

+98 86 3222 2003

##### **Email**

pr\_valieasr@arakmu.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Davood Hekmatpou

##### **Street address**

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

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3848176341

##### **Phone**

+98 86 3417 3532

##### **Email**

dr\_hekmat@arakmu.ac.ir

#### **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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## Person responsible for updating data

### 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**

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## Person responsible for scientific 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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**Postal code**

3848176341

**Phone**

## 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