

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluation of the quality of ventilation by the mask in three techniques: E-C, Thenar Eminence and X

#### Protocol summary

##### Study aim

Evaluation of ventilation quality by mask in three techniques E-C, Thenar Eminence and X

##### Design

Clinical trial, with parallel group, Not blinded, non randomized, on 310 patients.

##### Settings and conduct

All patients referred to the emergency department of Imam Reza Hospital, and who need an airway management, after obtaining the consent of the patient's guardian (considering that some patients referred to the emergency department are not in a position to obtain consent from them due to their clinical condition , Respiratory distress, etc. is not possible. After, pre-oxygenation, pre-medication and induction of anesthesia, patients are ventilated by a bag and mask attached to a capnogram by an emergency medicine specialist, senior resident. RESPIRONICS brand is used, depending on whether patients are in group I, II or III, after induction of anesthesia, it is ventilated 8 times by Bag and Mask, and at the end of each ventilation, ETCO<sub>2</sub> is recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients need a reliable airway that is indicated for fast-sequence intubation. Exclusion criteria: Patients who should be intubated by crash or awake method, as well as obese people, patients who have nasopharyngeal tube, patients with facial abnormalities, history of MALIGNANT HYPERTHERMIA, burns more than ten percent grade 3, peritonitis more than Three days, and Patients that have a long beard and mustache.

##### Intervention groups

Patients in need of reliable airway that are indicated for intubation in rapid sequence

##### Main outcome variables

The X method is easy to use for doctors with small hands and is a long-term use without fatigue and finger pain. If the quality of ventilation in X method is better than E-C and Thenar Eminence methods, it can be recommended, and the X method is a new method.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121010011067N5**

Registration date: **2021-07-17, 1400/04/26**

Registration timing: **prospective**

Last update: **2021-07-17, 1400/04/26**

Update count: **0**

##### Registration date

2021-07-17, 1400/04/26

##### Registrant information

##### Name

Mahboub Pouraghaei

##### Name of organization / entity

Tabriz University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 2078

##### Email address

pouraghaeim@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-06, 1400/05/15

##### Expected recruitment end date

2022-02-04, 1400/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the quality of ventilation by the mask in three techniques: E-C, Thenar Eminence and X

## Public title

Evaluation of the quality of ventilation by the mask in three techniques: E-C, Thenar Eminence and X

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients who need airway management and intubation that they need intubation with rapid sequence intubation

### Exclusion criteria:

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **310**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, participants will be unaware of the allocation of study groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Imam Reza Hospital, Tabriz University of Medical Sciences, Golegasht St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5356136883

#### Approval date

2020-07-13, 1399/04/23

## Ethics committee reference number

IR.TBZMED.REC.1399.383

## Health conditions studied

### 1

#### Description of health condition studied

Patients need airway

#### ICD-10 code

T88.4

#### ICD-10 code description

Failed or difficult intubation

## Primary outcomes

### 1

#### Description

Opening the airway

#### Timepoint

Patients that need airway, after induction of anesthesia, are ventilated 8 times by Bag and Mask.

#### Method of measurement

After induction of anesthesia, patients are ventilated 8 times by Bag and Mask and at the end of each ventilation, ETCO<sub>2</sub> is recorded.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Group 1: Patients who are ventilated by the E-C technique in which the first and second fingers of the resuscitator in the form of the letter C surround the mask pad and the next three fingers in the form of the letter E, surround the lower jaw (mandible). The RESPIRONICS brand capnogram device and the product of Respironics, Inc. with the specifications of Cosmas Court 2271 and Carlsbad, CA USA 92009 will be used.

#### Category

Treatment - Devices

### 2

#### Description

Group 2: Patients who are ventilated using the Thenar Eminence technique, in which the tenar muscles and the first finger of the resuscitator surround the mask pad and the next four fingers of the lower jaw.

#### Category

Treatment - Devices

### 3

#### Description

Group 3: Patients who are ventilated using the X-

technique, in which the palm of the resuscitator rests on the front of the pillow and her fingers guide the patient up to the chin

**Category**

Treatment - Devices

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Mahboub pouraghaei

**Street address**

Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht St

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

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**Phone**

+98 41 3335 2078

**Email**

pouraghaeim@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahboub Pouraghaei

**Street address**

Tabriz

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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**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahboub Pouraghaei

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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## Person responsible for updating data

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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**

There is no more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable