

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, ETCO₂ 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

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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, Golgasht 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, ETCO₂ 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 Respirationics, 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Street address

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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 scientific inquiries

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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