Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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, 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 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

5356136883

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

City

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

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East Azarbaijan

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Phone

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Email

pouraghaeim@yahoo.com

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

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Phone

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Email

pouraghaeim@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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Professor

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Person responsible for updating data

Contact

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Tabriz University of Medical Sciences

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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