

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparing the use of laryngeal mask airway (LMA) with tracheal tube to perform percutaneous dilatation tracheostomy (PDT) in brain trauma (TBI) patients.

Protocol summary

Study aim

Comparison of percutaneous dilatation tracheostomy (PDT) using laryngeal mask airway (LMA) with intubation method in brain trauma (TBI) patients

Design

A controlled, parallel-group, open-label, randomized, phase 2 clinical trial on 150 patients. The software of the website: www.random.org was used for randomization.

Settings and conduct

This study will be a prospective open label randomized clinical trial with that will be conducted by the ethics committee of Mazandaran University of Medical Sciences. After providing informed written consent, all patients assigned for transcutaneous tracheostomy were randomly divided into 2 groups using tracheal tube (control group) or laryngeal mask (intervention group) at Imam Khomeini Hospital in Sari city. Randomization will be achieved by a random list generated by a computer. For randomization, the rand function of Excel software was used. The patient information is collected by the nurse or the ward's secretary and then the information is delivered to the statistical specialist for analysis without the type of patient group.

Participants/Inclusion and exclusion criteria

Brain-injured patients admitted to the intensive care unit requiring long-term respiratory care. Patients with contraindications for PDT include an inadequate and difficult airway, potentially difficult endotracheal intubation, oxygenation index less than 200, and Positive end expiratory pressure (PEEP) ≥ 15 mbar will be excluded from the study.

Intervention groups

Control group: patients who are ventilated with a tracheal tube. Intervention group: patients who use a larynx mask in their ventilation.

Main outcome variables

Visualization of intratracheal structures during

tracheostomy placement.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211010052718N3**

Registration date: **2023-09-03, 1402/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-03, 1402/06/12**

Update count: **0**

Registration date

2023-09-03, 1402/06/12

Registrant information

Name

alireza nikzad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 3539

Email address

a.nikzad@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the use of laryngeal mask airway (LMA) with tracheal tube to perform percutaneous dilatation tracheostomy (PDT) in brain trauma (TBI) patients.

Public title

Comparing the use of laryngeal mask airway (LMA) with tracheal tube to perform percutaneous dilatation tracheostomy (PDT) in brain trauma (TBI) patients.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with brain injury hospitalized in the intensive care unit who need long-term respiratory care

Exclusion criteria:

Patients who had contraindications for Percutaneous DilatedTracheostomy included inadequate and difficult airway Patients who had contraindications forPercutaneous DilatedTracheostomy included obese subjects Patients with contraindications for Percutaneous DilatedTracheostomy included potentially difficult endotracheal intubation Patients with contraindications forPercutaneous DilatedTracheostomy included oxygenation index (Pascal Oxygen2/Fraction of Inspired Oxygen2) less than 200 Patients with contraindications for Percutaneous DilatedTracheostomy included positive end-expiratory pressure (Positive end-expiratory pressure) ≥ 15 mbar

AgeFrom **20 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **150****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients after choosing and obtaining informed consent to participate in the study after explaining the steps of conducting the research using the Simple Random Allocation method using a table of random numbers by computer and online (using the website www.random.org/integres) as They were randomly divided into two groups, A and B, each of which had its own code. These codes were written on the final envelope in which the patient group was specified. Without knowing these codes, the research colleagues placed the patients in one of the two groups by selecting each envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Imam Khomeini Hospital of Sari - Mazandaran University of Medical Sciences

Street address

Office Building Ethics Committee of Imam Khomeini Hospital Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

48166-33131

Approval date

2022-12-14, 1401/09/23

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1401.052

Health conditions studied**1****Description of health condition studied**

Diffuse traumatic brain injury

ICD-10 code

S06.2X

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes**1****Description**

Determining the quality of tracheostomy

Timepoint

Before and after the presser

Method of measurement

Arterial blood gas levels

Secondary outcomes**1****Description**

Comparison of the amount of time of two methods

Timepoint

before and after

Method of measurement

Record the time of the procedure from the beginning to the end

Intervention groups

1

Description

Intervention group: patients who are ventilated with a laryngeal mask, first the Endotracheal tube(ETT) was removed and then a Laryngeal mask airway(LMA Classic™) (purchased from Saba kompani, Iran) or a disposable LMA was implanted. LMA size was 4 in women and 5 in men. Then the LMA was fixed with glue and the patient's head was pulled. Inspiratory pressure was adjusted to reduce excessive air leakage when necessary. The video bronchoscope was inserted into the trachea through the LMA and the thyroid and cricoid cartilages and the upper 3 cartilages of the trachea were identified. After this, the tip of the bronchoscope was placed zero to one centimeter below the vocal cords to observe the thyroid cartilage.

Category

Treatment - Devices

2

Description

Control method: In patients who are ventilated with a tracheal tube, the cricoid and thyroid cartilages are touched and the position of the first tracheal cartilage is determined. Then the bronchoscope was inserted into the ETT up to the tip of the Endotracheal tube(ETT). After that, the ETT (purchased from Saba kompani, Iran) and the bronchoscope were placed directly above the specified position. This step was seen by transillumination and supported by another person responsible for positioning and stabilizing the ETT. Besides inspiratory pressure, ventilation variables were not modified. ETT size in women was 7.5-0.7 mm (inner diameter) and in men 0.8-7.5 mm. Percutaneous dilatational tracheostomy(PDT) was performed according to the Griggs method (31). After cutting the skin, the tracheal hole was guided by bronchoscopy to the midline of the trachea under the first or second tracheal cartilage. With the guidance of the guidewire, the dilatation process was checked with the Griggs dilating forceps and the guidance of the tracheostomy tube was also checked bronchoscopically. Before connecting to the ventilator, the intratracheal position of the cannula was confirmed by tracheobronchoscopy through the tracheostomy tube.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Medical Center

Full name of responsible person

Alireza Nikzad

Street address

Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

33131 - 48166

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

A.NIKZAD@MAZUMS.AC

Web page address

<http://mazums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

Street address

Moalem Ave

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3325 7230

Fax

+98 11 3325 7230

Email

m.saedi@mazums.ac.ir

Web page address

<http://mazums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Alireza Nikzad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

33131 - 48166

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

A.NIKZAD@MAZUMS.AC

Web page address

<http://mazums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Alireza Nikzad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

33131 - 48166

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

A.NIKZAD@MAZUMS.AC

Web page address

<http://mazums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Alireza Nikzad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

33131 - 48166

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

A.NIKZAD@MAZUMS.AC

Web page address

<http://mazums.ac.ir>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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