

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A double blind randomized controlled clinical trial study of comparison between two method of minisurgical percutaneous dilated tracheostomy, the standard method (Use of Tracheal Tube) or I gel insertion

Protocol summary

Study aim

The comparison between two method of PDT insertion technique, the standard method and I GEL implication .

Design

In this study, 66 patients were candidates for PDT and were eligible to enter the study. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct

This study, conducted as a double-blind clinical trial, was conducted at Masih Daneshvari Education and research Center, Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients under mechanical ventilation which They will have needs to maintain the tracheal tube more than 1 week; Lacking evidence of ischemic heart disease; Without any damage to the cervical spine; Without morbid obesity; The PT, PTT, INR and platelet in normal range. Exclusion criteria: No informe conscense; Failure in the relevant procedure.

Intervention groups

In the Conventional Method that will perform with ETT it will retract till to vocal cords to open enough space for the catheter insertion.

Main outcome variables

The control of tracheal puncture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020592N8**

Registration date: **2018-01-13, 1396/10/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-13, 1396/10/23**

Update count: **0**

Registration date

2018-01-13, 1396/10/23

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Masih Daneshvari Hospital the Edjucational , Research and Treatment center.

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double blind randomized controlled clinical trial study of comparison between two method of minisurgical percutaneous dilated tracheostomy, the standard method (Use of Tracheal Tube) or I gel insertion

Public title

The Comparison between two method of minisurgical

percutaneous dilated tracheostomy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients under mechanical ventilation which They will have needs to maintain the tracheal tube more than 1 week. Lacking evidence of ischemic heart disease. Without any damage to the cervical spine. Without morbid obesity. The PT , PTT, INR and platelet in normal range.
Exclusion criteria:
 No inform consent; Failure in the relevant procedure.

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The groups randomization will performed based on the A and B allocation group. this process will managed by computerizing allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
With regard to blindness, the study of the patient and the person who carries out the PDT is blind to the study, and the third person who is nurse in the department who is unaware of the study, are filling the questionnaire.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Masih Daneshvari Hospital the Edjucational , Research and Treatment center.
Street address
 Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
City
 Tehran

Province
Tehran
Postal code
 1956944413
Approval date
 2017-10-04, 1396/07/12
Ethics committee reference number
 IR.SBMU.NRITLD.REC.1396.378

Health conditions studied

1

Description of health condition studied
 The relationship between two methods of small throat surgery through the skin
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 The control of tracheal puncture
Timepoint
 During the process
Method of measurement
 Check list

2

Description
 Duration of the procedure
Timepoint
 During the process
Method of measurement
 Based on minutes

3

Description
 Peripheral blood oxygen saturation
Timepoint
 During the process
Method of measurement
 In terms of the oximeter pulse number

Secondary outcomes

1

Description
 Abnormal bleeding from Trachea.
Timepoint
 During the procedure
Method of measurement
 Based on clinical status

2

Description

Pneumothorax
Timepoint
During the procedure
Method of measurement
Based on clinical status

3

Description
Subcutaneous emphysema
Timepoint
During the procedure
Method of measurement
Based on clinical status

4

Description
Arrhythmia
Timepoint
During the procedure
Method of measurement
Based on electrocardiogram monitor monitoring

Intervention groups

1

Description
In the Conventional Method that will perform with ETT it will retract till to vocal cords to open enough space for the catheter insertion.
Category
Treatment - Surgery

2

Description
In Igel Method after the airway assessment and patient suctioning (to avoid aspiration), the Igel will be lubricated by gelly lubricant and it will be inserted orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital the Educational ,
Research and Treatment center
Full name of responsible person
Dr Seyyed Mohamadreza Hashemian
Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Masih Daneshvari Hospital
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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
Masih Daneshvari Hospital
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
Masih Daneshvari Hospital
Full name of responsible person
Dr Seyyed Mohammadreza Hashemian
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Latest degree

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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
to consider ethical problem

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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