

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

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 lubricated by gelly lubricant and it will inserted orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital the Edjucational ,
Research and Treatment center

Full name of responsible person

Dr Seyyed Mohamadreza Hashemian

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2912 3100

Email

iran.criticalcare@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Masih Daneshvari Hospital

Full name of responsible person

Dr. Seyyed Mohammadreza Hashemian

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2912 3100

Email

iran.criticalcare@yahoo.com

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

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid

Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 27123101

Fax

Email

iran.criticalcare@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Masih Daneshvari center

Full name of responsible person

Dr Seyyed Mohammadreza Hashemian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid

Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2912 3100

Fax

Email

iran.criticalcare@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Masih Daneshvari Center

Full name of responsible person

Dr Somayeh Akhavan

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid

Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2912 3100

Fax

Email

SOMAYEHAKHAVAN30@GMAIL.COM

Web page address

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