

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of Semi-surgical Percutaneous Dilatational Tracheostomy With Method of Conventional Percutaneous Tracheostomy: A Prospective Randomized Study

Protocol summary

Summary

(1) Objectives, The aim of this study is comparison of semi-surgical percutaneous dilatational tracheostomy (SSPDT) With method of conventional percutaneous dilatational tracheostomy (PDT). (2) Design, In a randomized clinical trial after approval of the ethics committee of the Babol University of Medical Sciences, 160 hospitalized patients in the ICU of rohani hospital, babol, who needed tracheostomy were enrolled to two equal groups of PDT and SSPDT. (3) Setting and conduct, after taking written consent about type of surgery, all patients receive midazolam 0.05 mg/kg, fentanil 2µg/kg. In conventional PDTgroup the needle is inserted blindly into the trachea and a Seldinger-type guide wire (Ciaglia Blue Rhino method) is placed into the lumen of the trachea. The stoma is then created by passing single dilators over the wire and a guiding catheter. In SSPDT group dissection (1.5 cm horizontal) is high in the neck 1cm below the cricoid cartilage to visualize easier and more convenient access to the trachea from the skin surface (4) Inclusion criteria: All patients requiring tracheal intubation for more than 14 days. Exclusion criteria: emergency tracheostomy, anterior cervical infection, enlargement of the thyroid gland; coagulation disorders, age younger than 18. (5) Intervention, In SSPDT group dissection (1.5 cm horizontal) is high in the neck 1cm below the cricoid cartilage. (6) Main outcome measures (variables), duration of receiving mechanical ventilation and ICU stay, complications of tracheostomy including bleeding, pneumothorax, stomal infection and accidental decannulation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602297752N8**

Registration date: **2016-03-09, 1394/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-09, 1394/12/19

Registrant information

Name

Parviz Amri Maleh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Semi-surgical Percutaneous Dilatational

Tracheostomy With Method of Conventional Percutaneous Tracheostomy:A Prospective Randomized Study

Public title

Comparison of Semi-surgical Percutaneous Dilatational Tracheostomy With Method of Conventional Percutaneous Tracheostomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:All patients requiring tracheal intubation for more than 14 days. Exclusion criteria : emergency tracheostomy; anterior cervical infection, enlargement of the thyroid gland; coagulation disorders, age younger than 18

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences,Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran

City

Babol

Postal code

471764136

Approval date

2016-01-17, 1394/10/27

Ethics committee reference number

MUBABOL.REC.1394.266

Health conditions studied

1

Description of health condition studied

Tracheostomy

ICD-10 code

J95.0

ICD-10 code description

Tracheostomy malfunction

Primary outcomes

1

Description

Bleeding

Timepoint

Intraoperation,72 hours after surgery

Method of measurement

Mililitr

2

Description

Infection

Timepoint

Intraoperation

Method of measurement

minute

3

Description

surgical time

Timepoint

Intraoperation

Method of measurement

minute

Secondary outcomes

1

Description

Hypoxia

Timepoint

Interaoperative

Method of measurement

Sao2 under 94%

Intervention groups

1

Description

Intervention: semi-surgical percutaneous dilatational tracheostomy

Category

Treatment - Surgery

2

Description

Control:conventional percutaneous dilatational tracheostomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani Teaching Centre

Full name of responsible person

Amri Maleh Parviz

Street address

Rohany teaching Hospital, Ganjafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Moghaddamnia Ali

Street address

Babol University of Medical Sciences, Gangafrooz St, Daneshgah Square, Babol, Iran

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Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for research, Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Vice-chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Amri Maleh Parviz

Position

Associated professor/Anesthesiologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty