Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 rhohani 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 Siences

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 surgury

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
City
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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
City
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
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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