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, fentanyl 2 µg/kg. In conventional PDT group 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 1 cm 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 1 cm 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)
Phone
+98 11 1223 8296
Email address
pamrimaleh@mubabol.ac.ir
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
Double blinded

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
Millilitr

2

Description
Infection

Timepoint
Intraoperation

Method of measurement
minute

3

Description
Hypoxia

Timepoint
Interaoperative

Method of measurement
Sao2 under 94%

Secondary outcomes

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
Babol

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
empty
Grant code / Reference number
empty
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
Street address
Rohny Hospital, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran
City
Babol
Postal code
4717641376
Phone
+98 11 4207 4589
Fax
+98 11 3223 8284
Email
pamrimaleh@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Amri Maleh Parviz
Position
Associated professor/Anesthesiologist
Other areas of specialty/work
Street address
Rohny Hospital, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran
City
Babol
Postal code
4717641376
Phone
+98 11 4207 4589
Fax
+98 11 3223 8284
Email
pamrimaleh@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Amri Maleh Parviz
Position
Associated professor/Anesthesiologist
Other areas of specialty/work
Street address
Rohny Hospital, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran
City
Babol
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Postal code
4717641376
Phone
+98 11 4207 4589
Fax
+98 11 3223 8284
Email
pamrimaleh@yahoo.com
Web page address

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