Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of body position Change on the endotracheal tube cuff pressure in patient hospitalized in intensive care unit.

Protocol summary

Summary

Aim of this study is a survey effect of changes in body position and head of bed on endotracheal tube cuff pressure in patient hospitalized in intensive care unit. 29 Patients who admitted to critical care unit and have inclusion criteria include, Age above 18 years old; Oral Endotracheal tube, Richmond sedation score -3 to -5; receiving mechanical ventilation for more than 24 hour and less than a week; systolic blood pressure more than 90 mm Hg and normal tempreture are selected. First the patients will be placed in a neutral position (30° angle to the head of the bed and head towards the body) for initiating data collection. Then the patient's position will change in each half hours sequence determined by researcher; left lateral position with a 30° angle to the head of the bed and head towards the body, right lateral position with a 30° angle to the head of the bed and head towards the body, left lateral position with 45° angle to the head of the bed and head towards the body, right lateral position with a 45° angle to the head of the bed and head towards the body. In each patient's change position, endotracheal tube cuff pressure will measure and record immediately before and after change position,and after 10 minutes .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051817735N1**
Registration date: **2016-04-15, 1395/01/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-15, 1395/01/27

Registrant information

Name
Mehdi Miri

Name of organization / entity
Torbat-e- Heydarieh University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 53 1222 8020

Email address
mirim1@thums.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of body position Change on the endotracheal tube cuff pressure in patient hospitalized in intensive care unit.

Public title

The effect of body Change position on the endotracheal tube cuff pressure.

Purpose

Prevention

Inclusion/Exclusion criteria

Participant: the subjects included in the study were above 18 years old with oral endotracheal tube whose Richmond sedation score were between 3-5. They had

received mechanical ventilation for less than a week, had normal body tempreture and their systolic blood pressure were above 90 mmHg. Those whose endotracheal cuff tube pressure rised above 50 mmHg for more than half an hour after the intervention were subject to exclusion.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **29**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sabzevar University of Medical Sciences

Street address
Asad Abadi st.

City
Sabzevar

Postal code

Approval date
2015-06-22, 1394/04/01

Ethics committee reference number
IRCT.MEDSAB.REC.1394.37

Health conditions studied

1

Description of health condition studied
acute respiratory failure

ICD-10 code
J96.0

ICD-10 code description
acute respiratory failure

Primary outcomes

1

Description
cuff pressure

Timepoint
Befor intervention, immediately after intervention

Method of measurement
Pressure is controlled by a mercury manometer according mm Hg .

Secondary outcomes

empty

Intervention groups

1

Description
Through the first intervention after the first subjects were positioned in a basic position lying on a bed declined about 30 degree with head aligned the body. Then the endotracheal cuff tube pressure is measured with a standard manometer in therm of mmHg. If needed the subjects' condition will be studied based on different positions subjects will take (lying on the left with head aligned the body on a bed in 30 degree position, lying on the right with head aligned the body again on a bed in 30 degree position, being semi setting on a bed in 45 degree with head aligned the body, and finally lying on the left and right respectively on a bed in 45 degree position with head aligned the body). The cuff tube pressure is measured each time. The subjects' position is change instantly before and after the change.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
9 Day Hospital

Full name of responsible person
Mehdi Miri

Street address
Parastar st.

City
Torbat-e-Heydarie

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Dr Mohamad Mohamadzade

Street address
Sabzevar
City
Sabzevar
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Mehdi Miri
Position
Student of MSc.
Other areas of specialty/work
Street address
Asad Abadi st.
City
Sabzevar
Postal code
Phone
+98 51 4401 1000
Fax
Email
MEHDI.MIRI11@YAHOO.COM MIRIM1@THUMS.AC.IR
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Zahra Estaji
Position
MSc
Other areas of specialty/work
Street address
Asad Abadi st.
City
Sabzevar
Postal code
9613873136
Phone
+98 51 4401 1000
Fax
Email
z.estaji@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mehdi Miri
Position
Clinical Nurse Spacialist student
Other areas of specialty/work
Street address
Asad abadi st.
City
Sabzevar
Postal code
Phone
+98 51 4401 1000
Fax
Email
MEHDI.MIRI11@YAHOO.COM MIRIM1@THUMS.AC.IR
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