

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effect of change position on endotracheal and intra-abdominal pressure.

Protocol summary

Summary

Aim of this study is a survey effect of changes in body position on endotracheal tube cuff pressure and intra-abdominal pressure. 60 Patients who admitted to critical care unit and have inclusion criteria include, age above 18 years old, connect to mechanical ventilation at least 24 hours and stable clinical condition are selected. Patients who have abnormality in airway and asynchronize with mechanical ventilation are excluded. At first in supine position endotracheal cuff pressure and intra-abdominal pressure are measured. Then the patients are randomly placed on positions: 30 degree, 45 degree, 30 degree front of mechanical ventilation and 30 degree backward to mechanical ventilation. Endotracheal tube cuff pressure and intra-abdominal pressure are measured after 5 minute pause in each position. Then effect of change position on intra-abdominal pressure and endotracheal cuff pressure are evaluated.

General information

Acronym

Effect of changes in body position on the endotracheal tube cuff pressure and intra-abdominal press

IRCT registration information

IRCT registration number: **IRCT201509176481N7**

Registration date: **2015-10-22, 1394/07/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-22, 1394/07/30

Registrant information

Name

Mohsen Soleimani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2015-11-21, 1394/08/30

Expected recruitment end date

2017-08-21, 1396/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of change position on endotracheal and intra-abdominal pressure.

Public title

Effect of change position on endotracheal cuff pressure and intra-abdominal pressure.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age above 18 years old; Connection to mechanical ventilation at least 24 hours; Richmond sedation score -3 to -5; and Exclusion criteria: Hemodynamic instability; Body temperature above 38 or below 35 centigrade; Lack of coordination between patient and mechanical ventilation; Abnormal disorder in airway

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, 5km
Damghan road, Semnan, Iran.

City

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Postal code

Approval date

2015-08-25, 1394/06/03

Ethics committee reference number

IR.Semums.Rec.1394.68

Health conditions studied

1

Description of health condition studied

Patients with mechanical ventilation

ICD-10 code

J96.0

ICD-10 code description

Acute respiratory failure

Primary outcomes

1

Description

Endotracheal cuff pressure

Timepoint

5 minutes after change position

Method of measurement

Gauge of pressure- cmH2o

Secondary outcomes

1

Description

Intra-abdominal pressure

Timepoint

5 minutes after change position

Method of measurement

column of water- cmH2O

Intervention groups

1

Description

Change position of bed to 30 degree, 45 degree and change position of body to front of mechanical ventilation and back to mechanical ventilation apparatus.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital in Shahrood

Full name of responsible person

Rasool Ashrafi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Ali Rashidipoor

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Semnan University of Medical Sciences, End of Basij
Avenue, Semnan, Iran.

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

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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