Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment the effect of changing body position on endotracheal tube cuff pressure in head trauma patients with mechanical ventilation who admitted in ICU ward

Protocol summary

Summary

Aim: Assessment the effect of changing body positions on endotracheal tube cuff pressure in head trauma patients along with mechanical ventilation who admitted in ICU wards. Main inclusion criteria: Patients aged 18-65 from both genders, more than 72 hours of intubation will be included. Main exclusion criteria: Presence of neck trauma, limitation in neck movement due to any reason, spinal trauma. Sample size: 30 head trauma patients hospitalized in ICU. This study is a "before-after" single group study. 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. Tracheal tube cuff pressure in end-expiratory pause (for 4-5 seconds) of mechanical ventilation can be measured and recorded in cm water with a standard manometer, If the cuff pressure is in inappropriate level, endotracheal tube cuff pressure will adjust in the range of 27 cm H2o. Then the patient's position will change in each two 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, semi-upright position at 45° 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 15 minutes .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111318342N3**

Registration date: **2015-01-10, 1393/10/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-10, 1393/10/20

Registrant information

Name

Azam Mohammadi Alamouti

Name of organization / entity

Qazvin University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Qazvin University of Medical Sciences

Expected recruitment start date

2014-10-27, 1393/08/05

Expected recruitment end date

2015-01-25, 1393/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of changing body position on

endotracheal tube cuff pressure in head trauma patients with mechanical ventilation who admitted in ICU ward

Public title
Assessment the effect of body position during sleep on the pressure of the respiratory tract in brain injury patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: The included group will be 18-65 years old of both genders; They should not have intubated more than 72 hours; patients should be in a lull level of -5 according to Richmond scale; Patients should be in a level of 3-4 according to behavioral pain scale; Intra tube suction has not done through 30 min before measurement of cuff pressure; Intubation should be done using low pressure and high volume tracheal tubes made by the same factory. Exclusion criteria: Pregnancy; presence of any injury or movement limitation due to any reason in neck vertebrae; short neck confirmed by physical examination done by physician; spinal injuries; tracheal anomalies (tracheomalacia) confirmed by physician; Cushing's triad (heart rate less than 60 beats per minute; breathing rate less than 8 per minute; systolic blood pressure greater than 140 mmhg); multiple trauma patients; difficult intubation according to physician report; arm perimeter greater than 32 cm (BMI>30)؛ Temperature greater than 38.3 and less than 35 ° C؛ respiratory rate greater than 35 times per minute؛ heart rate greater than 100 beats per minute؛ systolic blood pressure less than 90 mm Hg؛ mean arterial pressure below 60 mmHg
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin university of medical sciences
Street address
Qazvin university of medical sciences, Shahid bahonar boulevard, Qazvin, Iran
City
Qazvin
Postal code
Approval date
2014-10-27, 1393/08/05
Ethics committee reference number
20/9384/د

Health conditions studied

1

Description of health condition studied
Head trauma
ICD-10 code
S09.7
ICD-10 code description
Multiple injuries of head

Primary outcomes

1

Description
Endotracheal tube cuff pressure
Timepoint
Immediately before and after and 15 minutes after intervention
Method of measurement
Manometer

Secondary outcomes

1

Description
Temperature
Timepoint
Immediately before and after and 15 minutes after intervention
Method of measurement
Thermometer

2

Description
Blood pressure
Timepoint
Immediately before and after and 15 minutes after intervention
Method of measurement
Sphygmomanometer

3

Description
Heart rate
Timepoint
Immediately before and after and 15 minutes after intervention
Method of measurement
Enumeration

4

Description
Respiritory rate
Timepoint
Immediately before and after and 15 minutes after intervention
Method of measurement
Enumeration

5

Description
Mean airway pressure
Timepoint
Immediately before and after and 15 minutes after intervention
Method of measurement
Mechanical ventilation device

Intervention groups

1

Description
First the patients will be placed in a neutral position (° angle to the head of the bed and head towards the body) for initiating data collection. Tracheal tube cuff pressure in end-expiratory pause (for 4-5 seconds) of mechanical ventilation can be measured and recorded in cm water with a standard manometer, If the cuff pressure is in inappropriate level, endotracheal tube cuff pressure will adjust in the range of 27 cm H2o. Then the patient's position will change in each two 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, semi-upright position at 45° 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, after 15 minutes and finally after 2 hours. Patient's body core temperature, blood pressure, respiratory rate and heart rate will measure before and after change position, after 15 minutes and finally after 2 hours using infrared thermometer and monitoring devices. Patients during the measurements should be at level 5 according to the Richmond Agitation Sedation Scale and based on behavioral pain scale , they should be at 3-4 level, otherwise they will be excluded.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee Hospital
Full name of responsible person
Azam Mohammadi Alamouti
Street address
Shahid Rajai Hospital, Padegan Street, Qazvin, Iran
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Qazvin University of Medical Sciences
Full name of responsible person
Dr.Fatemeh Mohammadi
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Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin, Iran
City
Qazvin
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, Qazvin 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

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Full name of responsible person

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Position

Master student of intensive care nursing

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