

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

Country

Iran (Islamic Republic of)

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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

20/9384/3

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

Respiratory 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 Rajaei 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

Razi Hospital

Full name of responsible person

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Street address

Razi Hospital, Shahid Babaei Street, Qazvin, Iran

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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

Qazvin University of Medical Sciences

Full name of responsible person

Azam Mohammadi Alamouti

Position

Master student of intensive care nursing

Other areas of specialty/work

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City

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Postal code

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