

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of patient's head position on endotracheal tube cuff pressure in mechanically ventilated patients

Protocol summary

Study aim

determination of the effect of patient's head position on endotracheal tube cuff pressure in mechanically ventilated patients

Design

quasi experimental study. Each sample will be used as his / her own control.

Settings and conduct

Samples will be selected from the Amol intensive Care unites. First, the patient is placed in a position with elevation position of 30 degrees and the head will be in a neutral position, without a rotation. The tube trachea balloon is then connected to a German VBM cuff pressure manometer and the cuff pressure is adjusted to 25 cm H₂O. During the process, the monitor does not separate the cuff. Each patient will be placed in 6 positions from the starting position. These positions are: anterior flexion, hyper extension , left lateral flexion, right lateral flexion, left rotation and right rotation. the patient will not return to the starting position after each measurement. Between each change position is distance at least of 5 minutes . Care should be taken during the change of position so that no traction is made in the trachea. When the patient is placed in the position, respiration is performed by end-expiratory ventilatory hold in the range of 4 to 5 seconds, and at the same time, the cuff pressure is measured and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-65 years old; oral endotracheal intubation with Supa tube; mechanical ventilation; Richmond Agitation-Sedation Scale = -5. Exclusion criteria: tracheostomy; high-frequency oscillatory ventilation; pron position; pregnancy; difficult intubation; neck surgery; 37.5 < core temperature < 35; BMI > 30; contraindication of change position; need to mouth or ETT suctioning

Intervention groups

Patients who have ETT through the mouth and are under mechanical ventilation

Main outcome variables

Endotracheal tube cuff pressure

General information

Reason for update

Acronym

ETT

IRCT registration information

IRCT registration number: **IRCT20110705006955N4**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **retrospective**

Last update: **2018-03-19, 1396/12/28**

Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Roghieh Nazari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2017-01-30, 1395/11/11

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

2018-01-31, 1396/11/11
Actual recruitment end date
2018-02-20, 1396/12/01
Trial completion date
empty

Scientific title
The effect of patient's head position on endotracheal tube cuff pressure in mechanically ventilated patients

Public title
The effect of patient's head position on endotracheal tube cuff pressure

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-65 years old Oral endotracheal intubation with Supra tube Mechanical ventilation Richmond Agitation-Sedation Scale = -5
Exclusion criteria:
Patients have tracheostomy High-frequency oscillatory ventilation Pron position Pregnancy Difficult intubation Neck surgery 37.5 < core temperature < 35 Severe obesity BMI > 30 contraindication of change position for example : spinal injury hemodynamic and respiratory instability need to oropharyngeal or endotracheal suction

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: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not 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 Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Moallem Sq.
City
Sari
Province
Mazandaran
Postal code
4617188455

Approval date
2017-03-20, 1395/12/30
Ethics committee reference number
IR.MAZUMS.REC.2857

Health conditions studied

1

Description of health condition studied
intubated patients

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
cuff pressure

Timepoint
base line and after change the head position (6 points)

Method of measurement
cuff pressure monitor

Secondary outcomes

empty

Intervention groups

1

Description
Changing the position of the patient's head: First, the patient is placed in the supine position with a 30 degree elevation. This position is the starting position and in this position, the head will be in a neutral position, without a rotation. The cuff pressure will be adjusted to 25 cm. Then the position of the patient's head will be changed to the 6 position stated above, and the cuff pressure will be measured in each position .

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hefdah-e-Shahrivar hospital

Full name of responsible person

roghieh nazari

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Dr Roghieh Nazari

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Roghieh Nazari

Position

PhD of Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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assistant professor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available