

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of changes in body position on patient's endotracheal tube cuff pressure in intubated patients with spontaneous breathing

Protocol summary

Study aim

Determining the effect of changing the patient's body position on the pressure of the tracheal tube cuff in patients with spontaneous breathing

Design

Single group clinical trial, Target sampling to achieve the desired volume, Sample size 40 people

Settings and conduct

After obtaining the consent of the patient's guardian and explaining the study stages in the special wards of Razi and Nohom day Torbat Heydariyeh hospitals and selecting the samples with the criteria of entering and leaving the study, patients are placed in the supine position lying on the back and head of the bed with an angle of 30 degrees. they take. The cuff of the tracheal tube is connected to the cuff pressure manometer and the pressure is adjusted to 25 cmh2o. After changing the positions to lying on the back with a bed angle of 45 and 30 and lying on the left and right side with a head angle of 30 degrees, the cuff pressure changes is recorded.

Participants/Inclusion and exclusion criteria

1-conscious consent of the patient's guardian to attend the research 2-Having an endotracheal tube With a High-Volume, Low-Pressure Cuff with an inner diameter of 7 to 8.5 mm and made by Supa 3- Permission of the treating physician to To change position 4- Spontaneous breathing in the normal range 5-Blood pressure in the normal range 6- body Temperature in the normal range 7- No history of respiratory disease 8- Richmond Agitation-Sedation Scale between -3 to -5 9- Do not take Respiratory dilator drug's until one hour before the procedure

Intervention groups

This study has a group on which the body change position in the studied positions is performed on this group and the cuff pressure of the tracheal tube is measured after the change of position.

Main outcome variables

Changing the status of patients under intubation to lying

on the right and left sides significantly increases the pressure of the tracheal tube cuff.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200702047984N1**

Registration date: **2020-07-09, 1399/04/19**

Registration timing: **retrospective**

Last update: **2020-07-09, 1399/04/19**

Update count: **0**

Registration date

2020-07-09, 1399/04/19

Registrant information

Name

hossein monfared

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3513

Email address

hoseinmonfared01@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

2019-10-23, 1398/08/01

Actual recruitment end date

2020-03-20, 1399/01/01

Trial completion date

2020-03-20, 1399/01/01

Scientific title

The effect of changes in body position on patient's endotracheal tube cuff pressure in intubated patients with spontaneous breathing

Public title

The effect of changes in body position on patient's endotracheal tube cuff pressure in intubated patients with spontaneous breathing

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients hospitalized in special wards of Torbat Heydariyeh hospitals Having an endotracheal tube With a High-Volume, Low-Pressure Cuff with an inner diameter of 7 to 8.5 mm and made by Supa Richmond Agitation-Sedation Scale between -3 to -5

Exclusion criteria:

The patient's guardian does not consent to continue the procedure Hemodynamic instability

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **40**Actual sample size reached: **40****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 gonabad University of Medical Sciences

Street address

Khorasan, Gonabad, Imam Khomeini Avenue, Medical University of Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-10-21, 1398/07/29

Ethics committee reference number

IR.GMU.REC.1398.112

Health conditions studied**1****Description of health condition studied**

Change of the endotracheal tube cuff pressure While changing the patient's body position In patients with endotracheal tube and spontaneous breathing

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

Primary outcomes**1****Description**

The patient's tracheal tube cuff pressure

Timepoint

Immediately, 10, 20 and 30 minutes after changing position

Method of measurement

endotracheal cuff Pressure manometer made by VBM ;Germany

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This group includes 40 patients admitted to intensive care units. These patients have a chip tube, breathe spontaneously, and are not connected to a ventilator. The intervention is to change the patient's position from the basic position (lying on the back of the bed at an angle of 30 degrees) to the positions lying on the left and right sides of the head with an angle of 30 degrees and lying on the back with the head at an angle of zero and 45 degrees. The chip tube pressure is recorded immediately, 10, 20, and 30 minutes after the status change.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nohom Dey hospital

Full name of responsible person

Dr.Hossein Azizi

Street address

Kashani Ave, Nohom dey Hospital

City

Torbat Heydarieh

Province

Razavi Khorasan

Postal code

3116695188

Phone

+98 51 5222 6020

Email

PR@thums.ac.ir

2

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Amir Eslamian

Street address

Emam reza Ave, Razi Hospital

City

Torbat heydarieh

Province

Razavi Khorasan

Postal code

9519654145

Phone

+98 51 5223 5012

Email

hosp@razihosp.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Jalal Mardaneh

Street address

Emam Khomeyni Ave., Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3514

Email

info@gmu.ac.ir

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Hossein Monfared

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Imam Khomeini Ave, Medical University of Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3513

Fax

+98 51 5722 3815

Email

hoseinmonfared01@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Hossein Monfared

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Phone

+98 51 5722 3513

Fax

+98 51 5722 3815

Email

hoseinmonfared01@gmail.com

Fax

+98 51 5722 3815

Email

hoseinmonfared01@gmail.com

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

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Hosein Monfared hoseinmonfared01@gmail.com Kokab Basiri Moghadam k.basiri@gmu.ac.ir

What processes are involved for a request to access data/document

Send a request to email and research documentation

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Hossein Monfared

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

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