

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of endotracheal suctioning on endotracheal tube cuff pressure in mechanically ventilated patients

Protocol summary

Study aim

The aim of this study was to evaluate the effect of endotracheal suctioning 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 units. A trained nurse assistant will work on data collection, and data will be collected between 8 AM and 8 PM. At this stage, there will be no aggressive intervention or a change position of the patient. If necessary, the patient will be excluded from the above interventions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-65 years old, orotracheal intubation, mechanical ventilation. Exclusion criteria: tracheostomy, high-frequency oscillatory ventilation, pron position

Intervention groups

experimental group: At first, the cuff pressure of patients who have ETT through the mouth and are under mechanical ventilation, will be measured and set on 22 centimeters H₂O. Then the patient will be suctioned with open method and the cuff pressure will be measured during suctioning and at 15, 30 and 60 minutes intervals.
control group: At first, the cuff pressure of patients who have ETT through the mouth and are under mechanical ventilation, will be measured and set on 22 centimeters H₂O. Then the cuff pressure will be measured at 15, 30 and 60 minutes intervals.

Main outcome variables

Endotracheal tube cuff pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110705006955N5**

Registration date: **2018-06-29, 1397/04/08**

Registration timing: **retrospective**

Last update: **2018-06-29, 1397/04/08**

Update count: **0**

Registration date

2018-06-29, 1397/04/08

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

2017-05-22, 1396/03/01

Expected recruitment end date

2018-03-03, 1396/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of endotracheal suctioning on endotracheal tube cuff pressure in mechanically ventilated patients

Public title

Effect of suction on cuff pressure

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-65 years old Oral endotracheal intubation
mechanical ventilation

Exclusion criteria:

Tracheostomy High-frequency oscillatory ventilation Pron
position

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: **61**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

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

2017-05-05, 1396/02/15

Ethics committee reference number

IR-MAZUMS.REC.2838

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

intubated patients

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

endotracheal tube cuff pressure

Timepoint

no suctioning, 15,30 and 60 minutes after suction

Method of measurement

cuff pressure monitoring

Secondary outcomes

empty

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

endotracheal suctioning: in this study, open method
were used for endotracheal suctioning. in this method, it
is necessary to open the respiratory circuit by
disconnecting the mechanical ventilator from the
ventilatory prosthesis, followed by suctioning with a
single-use, sterile catheter during 10-15 sec.

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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Hefdah-e-Shahrivar Street, Amol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Science

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 Science

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

Dr. Roghieh Nazari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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