Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparing the Open Endotracheal Suctioning and the Closed Endotracheal Suctioning Methods on the Level of Pain and Agitation of Patients under Mechanical Ventilation

Protocol summary

Summary

The aim of this study was comparing the effectiveness of the open and closed endotracheal suction tube system on the pain and agitation of patients under mechanical ventilation. The present study was a randomized controlled clinical trial on mechanically ventilated patients hospitalized in the intensive care units of selected hospitals in Tehran. Sixty mechanically ventilated patients who were qualified for being included in the study were randomly assigned to the intervention and the comparison groups using the blocks of four method. In case of a necessity, the suction was carried out for each patient using the standard technique. The patients' level of pain and agitation was measured in both group at five stages (before, during, immediately, 5 minutes, and 15 minutes after the intervention) using the behavioral pain scale and the Richmond Agitation Sedation Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508268650N6**
Registration date: **2016-04-01, 1395/01/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-01, 1395/01/13

Registrant information

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Abbas Ebadi

Name of organization / entity

Baqiyatallah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2015-04-01, 1394/01/12

Expected recruitment end date

2015-08-08, 1394/05/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Open Endotracheal Suctioning and the Closed Endotracheal Suctioning Methods on the Level of Pain and Agitation of Patients under Mechanical Ventilation

Public title

Comparing the Open Endotracheal Suctioning and the Closed Endotracheal Suctioning Methods on the Level of Pain and Agitation of Patients under Mechanical Ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The criteria for entering the study consisted of being 18 years of age or older, being an intubated (having a tube in the trachea) and

mechanically ventilated patient, having a consciousness level with a Glasgow coma score of 7 or higher, having vital signs within normal limits, not having taken high-dose sedatives and tranquilizers (deep sedition) during the past six hours, having no severe facial trauma, taking dopamine, dobutamine and nitroglycerin according to the physician's orders (not taking them in unconventional doses), having a normal hearing and speaking ability and not being dependent on utilities such as hearing aids, not suffering from a neurological damage affecting breathing (such as quadriplegia), having no record of mental illness and severe neurological problems, and not being affected by neuromuscular diseases. The exclusion criteria consisted of not receiving the patient's companion's consent, tracheal extubation, patient's being in need of repeated suctioning or suctioning in intervals shorter than 20 minutes, having a reduced level of consciousness during suctioning, dysrhythmia, suffering from a reduced SPO2 level more than 10% during suctioning, and being in need of tranquilizers and painkillers more than the common treatment protocol.

Age
From **18 years** old to **94 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University Ethics Committee Medical Branch of Tehran

Street address
Khaghani st, Shariati Ave, Tehran, Iran

City
Tehran

Postal code
193951495

Approval date
2016-02-24, 1394/12/05

Ethics committee reference number
IR.IAU.TMU.REC.1394.23

Health conditions studied

1

Description of health condition studied
Patients with impaired respiratory function in ICU

ICD-10 code
J95 , J96

ICD-10 code description
Other diseases of the respiratory system

Primary outcomes

1

Description
Severity of Pain

Timepoint
Before, during, immediately after the intervention, 5 minutes and 15 minutes after intervention

Method of measurement
BPS

Secondary outcomes

1

Description
Agitation

Timepoint
Before, during, immediately after the intervention, 5 minutes and 15 minutes after intervention

Method of measurement
Richmond Agitation Sedation Scale

2

Description
Heart rate

Timepoint
Before, during, immediately after the intervention, 5 minutes and 15 minutes after intervention

Method of measurement
Monitoring Device

3

Description
SPO2

Timepoint
Before, during, immediately after the intervention, 5 minutes and 15 minutes after intervention

Method of measurement
Monitoring Device

4

Description
respiration rate
Timepoint
Before, during, immediately after the intervention, 5 minutes and 15 minutes after intervention
Method of measurement
Monitoring Device

5

Description
Systolic Blood Pressure
Timepoint
Before, during, immediately after the intervention, 5 minutes and 15 minutes after intervention
Method of measurement
Monitoring Device

6

Description
Mean Arterial Blood Pressure
Timepoint
Before, during, immediately after the intervention, 5 minutes and 15 minutes after intervention
Method of measurement
Monitoring Device

7

Description
Diastolic Blood Pressure
Timepoint
Before, during, immediately after the intervention, 5 minutes and 15 minutes after intervention
Method of measurement
Monitoring Device

Intervention groups

1

Description
In the experimental group (open suction system) In the beginning, The vital signs were recorded by the monitor. The patient was then hyper-oxygenized with 100% oxygen. Immediately after that, endotracheal suctioning (open) was conducted rotationally for 10 to 15 seconds with a maximum pressure of 120 mm Hg. Following that, the patient was again hyper-oxygenated with 100% oxygen, and hemodynamic variables were recorded at five temporal stages for both groups with the monitoring device. The pain and agitation of the two groups were measured using the Richmond Agitation Sedation Scale at five temporal stages (before, during, immediately, 5 minutes after the suctioning, and 15 minutes after the suctioning).
Category
Prevention

2

Description
In the experimental group (close suction system) In the beginning, The vital signs were recorded by the monitor. The patient was then hyper-oxygenized with 100% oxygen. Immediately after that, endotracheal suctioning(close) was conducted rotationally for 10 to 15 seconds with a maximum pressure of 120 mm Hg. Following that, the patient was again hyper-oxygenated with 100% oxygen, and hemodynamic variables were recorded at five temporal stages for both groups with the monitoring device. The pain and agitation of the two groups were measured using the Richmond Agitation Sedation Scale at five temporal stages (before, during, immediately, 5 minutes after the suctioning, and 15 minutes after the suctioning).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam ol Anbia Hospital and Sina Hospital
Full name of responsible person
Razieh Dastdadeh
Street address
Tehran, Rashid Yasemi St
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of, Islamic Azad University branch of Medical Sciences Tehran
Full name of responsible person
Hasan Eftekhar Ardabili
Street address
Khaghani st, Shariati Ave, Tehran, Iran
City
Tehran
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 of, Islamic Azad University branch of Medical Sciences Tehran
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
School of Nursing and Midwifery, Islamic Azad University of Tehran
Full name of responsible person
Raziyeh Dastdadeh
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Web page address
www.bmsu.ac.ir

Person responsible for updating data

Contact

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