

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

Name

Abbas Ebadi

Name of organization / entity

Baqiyatallah University of Medical Sciences

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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 sedation) 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 Eftekhari Ardabili

Street address

Khaghani st, Shariati Ave, Tehran, Iran

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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
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Full name of responsible person

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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