Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparative study on the effect of tracheal suction with and without normal saline instillation on physiological indices and incidence of bronchospasm in patients undergoing mechanical ventilation

Protocol summary

Study aim

Comparison of the effect of tracheal suction with and without normal saline instillation on physiological indices and incidence of bronchospasm in patients undergoing mechanical ventilation.

Design

In this clinical trial, patients were selected based on merit criteria and assigned randomly to two groups. The study is done cross over.

Settings and conduct

In this study, performed on patients admitted to ICU, endotracheal suctioning was performed in both groups with and without normal saline instillation in the endotracheal tube, first suctioning for 12 hours or at least 4 times, in One group instillation normal saline and the other group without normal saline and then the two groups were replaced and suctioned for 12 hours or 4 times. Physiological indices were monitored and recorded immediately before suction and after suction at 4 times (immediately, 1, 5 and 10 minutes after suction) by the patient-connected monitor. The incidence of post-suction bronchospasm is also controlled by monitoring arterial oxygen saturation, inhalation pressure and expiratory volume.

Participants/Inclusion and exclusion criteria

Entry requirements: 1. The patient is admitted to ICU. 2. The patient is intubated and undergo mechanical ventilation. 3. The age of the patient is between 18 and 55 years. Non-arrival conditions: 1. History of heart and lung disease 2. unstable hemodynamic status 3. Acute respiratory failure 4. The patient has tracheostomy

Intervention groups

In this study, tracheal suctioning with and without normal saline instillation was performed in two groups of intervention and control and compared to the results.

Main outcome variables

Pulse changes, Blood Pressure changes, SpO2 changes and bronchospasm incidence is different in endotracheal suctioning without normal saline compared to normal saline.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190521043653N1**
Registration date: **2019-09-16, 1398/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-16, 1398/06/25**
Update count: **0**

Registration date

2019-09-16, 1398/06/25

Registrant information

Name

Ali Kamayestani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study on the effect of tracheal suction with and without normal saline instillation on physiological indices and incidence of bronchospasm in patients undergoing mechanical ventilation

Public title
Normal saline effect on tracheal suctioning process
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalization in Intensive Care Unit have a tracheal tube undergoing mechanical ventilation Ages 18 to 55 years
Exclusion criteria:
Acute respiratory failure Moderate and severe hypoxia The patient with tracheostomy A History of Cardio Pulmonary Disease
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with Inclusion Criteria were randomly assigned into two groups (the first patient with normal saline and the second patient without normal saline and so on). According to a Cross Over study, randomization has little effect on the research process.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
University of Medical Sciences campus, Shohadaye Hastei Blvd
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Approval date
2019-08-31, 1398/06/09
Ethics committee reference number
IR.MEDSAB.REC.1398.038

Health conditions studied

1

Description of health condition studied
Loss of consciousness
ICD-10 code
S06
ICD-10 code description
Intracranial injury

Primary outcomes

1

Description
Arterial oxygen saturation level
Timepoint
Immediately before suctioning the tracheal tube and immediately, 1, 5 and 10 minutes after suction.
Method of measurement
Monitor device of Sazgan Gostar Company, VECTRA model

Secondary outcomes

1

Description
Blood pressure
Timepoint
Immediately before suctioning the tracheal tube and immediately, 1, 5 and 10 minutes after suction.
Method of measurement
Monitor device of Sazgan Gostar Co. VECTRA model

2

Description
Heart rate
Timepoint
Immediately before suctioning the tracheal tube and immediately, 1, 5 and 10 minutes after suction.
Method of measurement
Monitor device of Sazgan Gostar Co. VECTRA model

3

Description
The incidence of bronchospasm
Timepoint
Immediately and 10 minutes after suction.
Method of measurement
Dräger ventilator. Made in Germany

Intervention groups

1

Description
Intervention group: Intubate patients whose suction is performed without normal saline instillation.
Category
Prevention

2

Description
Control group: Intubate patients whose suction is performed with normal saline instillation.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Ali Kamayestani
Position
Nurse
Latest degree
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Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available