

# 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)

##### Phone

+98 51 4467 2107

##### Email address

kamayestania94@medsab.ac.ir

##### 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

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Razavi Khorasan

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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**

Dr. Mohammad Sadegh Vaziri

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Razi Ave.

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### 2

**Recruitment center****Name of recruitment center**

Vasei Hospital

**Full name of responsible person**

Dr. Taha Hosseini Farahabadi

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

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vc.research@medsab.ac.ir

**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**

Bachelor

**Other areas of specialty/work**

Nursery

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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