

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

**Determine the effect of the artificial airway of open suctioning based on the standard criteria that need to have suction in the hemodynamic status and also pulmonary patients hospitalized in the intensive care units.**

### Protocol summary

#### Summary

The purpose of the study: The purpose of this study was to determine the effect of the artificial airway of open suctioning based on the standard criteria that need to have suction in the hemodynamic status and also pulmonary patients hospitalized in the intensive care units. Generally this study is designed based on the mentioned issues. The design of the study: This study is a randomized clinical trial (RCT) with a pretest and Post-Test design and with one control group. The participants of the study. Inclusion criteria: Having a minimum age of 18 and maximum age of 70 years! An artificial airway in the ventilator circuit! having vital signs within normal limits. Exclusion criteria: Not having cardiac and pulmonary monitoring, A serve heart or lung disease! Chronic obstructive disease high intracranial pressure! Pulmonary parameters and vital signs within normal limits! Dopamine medication! Dubatomin! nitroglycerin and increasing the blood pressure\_lowering drugs! Removal of the ventilator! And the patient death during the study! Having significant problem after the first suction or having an urgent need to have second suction! And also the patients who do not have suction problems (Airway bleeding! Fractures! Et) and the patients under cmv mode will not be considered in this study. The number of participants in each group was 30 and totally were 60 participants. The samples will be selected randomly and based on a randomized block allocation in the two groups will be compared. Standard criteria of suction will be designed based on the investigation of valid sources and references and after the evaluation of its validity with ten clinical experts of pulmonary experts, ICU, and also the faculty members of Tehran and Zanzan nursing medical Universities will be used for training mediatory nurses to suction the patients in the experimental group. Then the routine criteria will be

used to have artificial airway suctioning with the help of nurses in the intensive care units and they are based on the conducted interviews and observations. Then the standard suction method with other standard criteria in suctioning will be taught to control and experimental group nurses in the educational workshops. In the experimental group, the patients will be evaluated in terms of their need to artificial airway suction, and if needed, the suction will be performed by the standard methods. In the control group, having suction with standard protocol will be conducted but they are based on the routine criteria of suctioning. Finally, for each patient suction will be in three times and the measurement of dependent variables will be six times before and after each suction. The study will be lasted for 5 months. The main variables of the study: They included pulmonary hemodynamic status and Pulmonic parameters. In order to measure and record data on the hemodynamic and respiratory parameters through direct observation at the besides of patients, changes in the vital signs and hemodynamic status (Bp; MAP;RP;Spo2;HR) and respiratory parameters (TV; Resistance airway;Compliance; Pmean; MV) will be examined.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2015061012257N2**  
Registration date: **2015-08-15, 1394/05/24**  
Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2015-08-15, 1394/05/24

## Registrant information

### Name

Farhad Ramezani-Badr

### Name of organization / entity

Zanjan University of Medical Sciences

### Country

Iran (Islamic Republic of)

### Phone

+98 24 3527 9412

### Email address

ramazanibadr@zums.ac.ir

## Recruitment status

### Recruitment complete

## Funding source

Other costs will be paid by Vice chancellor for research (science and technology), ethical deputy committee, Zanjan University of Medical Sciences.

## Expected recruitment start date

2014-11-22, 1393/09/01

## Expected recruitment end date

2015-04-20, 1394/01/31

## Actual recruitment start date

empty

## Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Determine the effect of the artificial airway of open suctioning based on the standard criteria that need to have suction in the hemodynamic status and also pulmonary patients hospitalized in the intensive care units.

## Public title

Determine the effect of the artificial airway of open suctioning based on the standard criteria that need to have suction in the hemodynamic status and also pulmonary patients hospitalized in the intensive care units.

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Having a minimum age of 18 and maximum age of 70 years! An artificial airway Having vital signs within normal limits. Exclusion criteria: Not having cardiac and pulmonary monitoring! A serve heart or lung disease! Chronic obstructive disease high intracranial pressure! Pulmonary parameters and vital signs within normal limits! Dopamine medication! Dubatomin! Nitroglycerin and increasing the blood pressure\_lowering drugs! Removal of the ventilator! and the patient death during the study ! Having significant problem after the first suction or having an urgent need to have second suction! And also the patients who do not have suction problems (Airway bleeding! Fractures! et) and the patients under CMV made will not be considered in this study.

## Age

From **17 years** old to **80 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice chancellor for research(Science and Technology) , ethical deputy committee, Zanjan University o

##### Street address

University of Medical Sciences, Third floor of research department (Science and Technology) Vice chancellor for research, Zanjan medical University deartment, Zanjan. Iran.

##### City

Zanjan

##### Postal code

4515789589

#### Approval date

2014-11-22, 1393/09/01

#### Ethics committee reference number

zums.rec.1393.171

## Health conditions studied

### 1

#### Description of health condition studied

Patients with airway artificial lung

#### ICD-10 code

J95-J99

#### ICD-10 code description

Other diseases of upper respiratory tract

## Primary outcomes

## 1

### **Description**

Mean Arterial pressure

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

Mm Hg, by monitoring patients.

## 2

### **Description**

Blood pressure

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

Mm Hg, by monitoring patients.

## 3

### **Description**

Respiratory Rate

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

The minutes of number, by cardiac monitoring.

## 4

### **Description**

Saturation of arterial hemoglobin

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

Percentage minutes, by cardiopulmonary monitoring.

## 5

### **Description**

Resistance airway

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

Cm of H<sub>2</sub>O per minute, ventilator.

## 6

### **Description**

Heart rate

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

The minutes of number, by cardiac monitoring.

## 7

### **Description**

Tidal Volume

## **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

Cc per kg; ventilator.

## 8

### **Description**

Compliance

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

ml cm of H<sub>2</sub>O; ventilator.

## 9

### **Description**

Mean airway pressure

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

ventilator.

## 10

### **Description**

Minute volume

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

Cc per kg; ventilator.

## **Secondary outcomes**

## 1

### **Description**

intracranial pressure

### **Timepoint**

Before the five minutes after opening the airway suctioning artificial

### **Method of measurement**

Mm Hg, intracranial shunt

## 2

### **Description**

and the patient death during the study

### **Timepoint**

Before two and five minutes after opening the airway suctioning artificial

### **Method of measurement**

Questionnaire

## **Intervention groups**

## 1

### Description

Experimental group: After random sampling of the patients, The standard suction method with other standard criteria will be taught to working and volunteer nurses in both control and experimental groups. Then the control group nurses are asked to performed standard suction without consideration of standard criteria of suctioning. The participant nurses of this study have bachelor degree in nursing and their minimum working experience is about three years in ICU ward of Mousavi and Vali Asr hospitals that had passed scientific and standard principles of airway suction in the educational workshops. In the experimental group, the patients will be evaluated in terms of their need to have artificial airway suction based on the standard criteria and in the condition of necessity the suction will be performed in the standard method.

### Category

Prevention

## 2

### Description

Control group: in the control group, suction will be done based on routine standard criteria.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Mousavi Hospital, Zanjan. Iran.

##### Full name of responsible person

Farshid Alazmani Noodeh, Master Nursing Intensive Care.

##### Street address

Mousavi Educational Hospital, Gavazang Road, Zanjan. Iran.

##### City

Zanjan

### 2

#### Recruitment center

##### Name of recruitment center

Hazrat Vali Asr hospital, Zanjan. Iran.

##### Full name of responsible person

Farshid Alazmani Noodeh, Master Nursing Intensive Care

##### Street address

Vali Asr Educational Hospital, 22nd Farvardin Square, Zanjan. Iran.

##### City

Zanjan

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice chancellor for research (Science and Technology) , Zanjan University of Medical Sciences

#### Full name of responsible person

Vice chancellor for research (Science and Technology) , Zanjan University of Medical Sciences, Dr. Sogh

#### Street address

University of Medical Sciences, Third floor of research department (Science and Technology) Vice chancellor for research, Zanjan medical University department, Zanjan. Iran.

#### City

Zanjan

### 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 (Science and Technology) , Zanjan University of Medical Sciences

### 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

Zanjan University of Medical Sciences

#### Full name of responsible person

Farshid Alazmani Noodeh

#### Position

Master of intensive Nursing care

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## 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*