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 Zanjan 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

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Farhad Ramezani-Badr

Name of organization / entity
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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 deoartment, 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 H2O 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 H2O; 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
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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

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

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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