Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Comparison the effect of open and close endotracheal suctioning on hemodynamic status of patient with head trauma hospitalized in intensive care unit

Protocol summary

Summary

The aim of this study is comparing the effect of open and close endotracheal suctioning on hemodynamic status of patient with head trauma under mechanical ventilation. Design: 88 patients who needed endotracheal suctioning in SICU of Shahid Beheshti hospital on Babol University of medical science who were randomly allocated to undergo either closed (n=44) or open (n=44) suctioning. After getting oxygenated with 100% O2 for one minute, the patients are suctioned with either method for 15 seconds. They will also receive 100% oxygen for one minute after suctioning and then hemodynamic indices (Heart rate, Respiratory rate, Mean Arterial Pressure, Cardiac Dysrhythmia, Central venous pressure, Positive end expiratory pressure, Arterial Blood Oxygen Saturation) are compared after suctioning every five minutes up to fifteen minutes between two groups. This study is single-blind, parallel clinical trial. Inclusion criteria: Patients without lung problems, Age more than 12 years old, Head trauma, Level of consciousness between 4-8, Patients with Endotracheal tube, Hemodynamic stability, lack of dysrhythmia. Exclusion criteria: Patients require frequent suctioning, any serious adverse effects during study (increasing of intracranial pressure, severe impairment in hemodynamic status). Intervention: In one group closed suction method and in another one, open suction method will perform. Main outcome measures: evaluating changes in hemodynamic indices with two methods in head trauma patients.

General information

Acronym

SICU: Surgical Intensive Care Unit

IRCT registration information

IRCT registration number: **IRCT2015092624213N1**
Registration date: **2016-01-22, 1394/11/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name
Behrooz Dadkhah
Name of organization / entity
Ardabil University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 45 3351 1211
Email address
b.dadkhah@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Science

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of open and close endotracheal suctioning on hemodynamic status of patient with head

trauma hospitalized in intensive care unit

Public title
Endotracheal suctioning and hemodynamic status
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria; 1. Patients without lung problems 2. Age more than 12 years old 3. Head trauma 4. Level of consciousness between 4-8 5. Patients with Endotracheal tube 6. Hemodynamic stability 7. lack of dysrhythmia Exclusion criteria: 1. Patients require frequent suctioning 2. Any serious adverse effects during study(increasing of intracranial pressure, Severe impairment in hemodynamic status)
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **88**
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
Ethic committee of Ardabil University of Medical Science
Street address
Ethic committee unit, Vice chancellor for research, Ardabil University of Medical Science, Kosar town, Ardabil, Iran
City
Ardabil
Postal code
Approval date
2015-08-08, 1394/05/17
Ethics committee reference number
IR.ARUMS.1394.21

Health conditions studied

1

Description of health condition studied
head trauma
ICD-10 code
S00-S09
ICD-10 code description
Fracture of skull with associated intracranial injury, Fracture of vault of skull, Fracture of base of skull, Multiple superficial injuries of head

Primary outcomes

1

Description
Respiratory rate
Timepoint
Before and immediately after suctioning and then every five minutes up to fifteen minutes
Method of measurement
Observation and records

2

Description
Heart rate
Timepoint
Before, during and immediately after suctioning and then every five minutes up to fifteen minutes
Method of measurement
Observation and records

3

Description
Mean Arterial Pressure
Timepoint
Before, during and immediately after suctioning and then every five minutes up to fifteen minutes
Method of measurement
Observation and records

4

Description
Arterial Blood Oxygen Saturation
Timepoint
Before, during and immediately after suctioning and then every five minutes up to fifteen minutes
Method of measurement
Observation and records

5

Description
Cardiac dysrhythmia
Timepoint
During and Immediately after suctioning and then every five minutes up to fifteen minutes
Method of measurement

Observation and records

6

Description
Central Vein Pressure
Timepoint
Before and immediately after suctioning and then every five minutes up to fifteen minutes
Method of measurement
Observation and records

7

Description
Positive End Expiratory Pressure
Timepoint
Before, during and Immediately after intervention, Five, Ten, Fifteen minutes after open and close suction
Method of measurement
Observation and records

8

Description
Added at 2016-02-25: number of suctioning
Timepoint
Added at 2016-02-25: Before, during and immediately after suctioning and then every five minutes up to fifteen minutes
Method of measurement
Added at 2016-02-25: observation and records

Secondary outcomes

empty

Intervention groups

1

Description
After getting oxygenated with 100% O2 for one minute, the patients are suctioned with closed suction method for 15 seconds. The catheter will be inserted into the endotracheal tube and then will be withdrawn back for 0.5 cm. A negative pressure of maximum 20 KPa will be set, and catheter will be withdrawn. They will also receive 100% oxygen for one minute after suctioning.
Category
Prevention

2

Description
After getting oxygenated with 100% O2 for one minute, the patients are suctioned with closed suction method for 15 seconds. The catheter will be inserted into the endotracheal tube and then will be withdrawn 0.5 cm. A negative pressure of maximum 20 KPa will be set, and catheter will be withdrawn. They will also receive 100% oxygen for one minute after suctioning.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Surgical Intensive Care Unit of Shahid Beheshti Hospital
Full name of responsible person
Asieh Shabani Faramarzi
Street address
Shahid Beheshti Hospital, Keshvari Square, Babol, Mazandaran, Iran
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Babol University of Medical Sciences
Full name of responsible person
Shahram Habibzadeh
Street address
Vice chancellor for research, Headquarters, Ardabil University of Medical Science, Kousar town, Ardabil, Iran
City
Ardabil
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, Babol 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
Ardabil University of medical science
Full name of responsible person
Asieh Shabani Faramarzi
Position

Student of master degree in critical care nursing

Other areas of specialty/work

Street address

Number 39, Zoolfaghar Alley, Keshvari Square, Babol, Mazandaran, Iran

City

Babol

Postal code

4716758393

Phone

+98 11 3225 5939

Fax

Email

asiehshabanifaramarzi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of medical science

Full name of responsible person

Behrooz Dadkhah

Position

PhD of nursing

Other areas of specialty/work

Street address

Nursing and Midwifery faculty, Saedi street, Ardabil, Iran

City

Ardabil

Postal code

Phone

+98 45 3351 2877

Fax

Email

b.dadkhah@arums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Nursing and Midwifery faculty, Ardabil University of Medical Science

Full name of responsible person

Asieh Shabani Faramarzi

Position

Student of master degree in critical care nursing

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Number 39, Zoolfaghar Alley, Keshvari square, Babol, Mazandaran, Iran

City

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Postal code

4716758393

Phone

+98 11 3225 5939

Fax

Email

asiehshabanifaramarzi@gmail.com

Web page address

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