

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

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Behrooz Dadkhah

Name of organization / entity

Ardabil University of Medical Science

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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

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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