Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The comparison effect of combinational changes of catheter size and its related suction negative pressure on hemodynamic and respiratory parameters of patients undergoing mechanical ventilation

Protocol summary

Study aim
Determine the effect of combination changes of catheter size and negative suction pressure on hemodynamic and respiratory parameters in patients undergoing mechanical ventilation.

Design
Clinical trial without control group

Settings and conduct
Study will be done in the Shahid Beheshti and Imam Sajjad Hospitals in Yasuj. 1 minute before and after suction Oxygen will be 100% received and before connecting the catheter to the suction tube the negative suction pressure will be adjusted by blocking the end of the suction tube The suctioning catheter when struck, pull 1 cm back , suction will be performed 2 times for 10 seconds Between these ,the patient will be connected to the ventilator for 30 seconds

Participants/Inclusion and exclusion criteria
Inclusion criteria: Minimum age of 18 and up to 65 years, connecting to a fixed volume ventilator , at least 24 hours before intervention in the intensive care unit Hospitalized and and has a size of 7.5 in the trachea tube , Stable hemodynamic status , Have a score of -2 to -5 based on the Richmond scale. Exclusion criteria: Having respiratory illnesses like Asthma, emphysema, COPD and ARDS diagnosed by physician ,the use of positive inotropic drugs, such as dopamine and dobutamine 3- Severe cardiovascular and pulmonary failure , high intracranial pressure, score (-1 to 4+) based on Richmond's scale, blood coagulation disorder and thrombocytopenia

Intervention groups
35 patients in a single-group will be suctioned 4 times.initially with a catheter of 10 and a negative pressure of 100, second time a catheter of 10 and a negative pressure of 150 , third time a catheter of 12 and a negative pressure of 100 and fourth time the catheter size 12 and the negative pressure 150

Main outcome variables
Hemodynamic parameters and respiratory parameters will be recorded before, immediately, 10 and 20 minutes after suction.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190120042436N1**
Registration date: **2019-03-06, 1397/12/15**
Registration timing: **prospective**

Last update: **2019-03-06, 1397/12/15**
Update count: **0**

Registration date
2019-03-06, 1397/12/15

Registrant information

Name
Mohsen Salari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-09, 1397/12/18

Expected recruitment end date
2019-06-08, 1398/03/18

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison effect of combinational changes of catheter size and its related suction negative pressure on hemodynamic and respiratory parameters of patients undergoing mechanical ventilation

Public title
Effect of endotracheal suctioning on hemodynamic and respiratory parameters of patients undergoing mechanical ventilation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Minimum age 18 and maximum 65 years Having an endotracheal tube and connecting to fixed volume ventilator (SIMV-A / C) The patient should be admitted at least 24 hours before the intervention in the intensive care unit and under mechanical ventilation and has an endotracheal tube with diameter of 7.5. Stable hemodynamic status(Medium arterial pressure between 60-110 mm-Hg -Hypertension is more than 90 and less than 140- And diastolic pressure of less than 100 mm Hg-Heart rate less than 100 and more than 60 beats per minute -And oxygen saturation of arterial blood more than 90%) Have a score of -2 to -5 based on the Richmond Agitation Sedation Scale
Exclusion criteria:
Having respiratory illnesses like asthma, emphysema,COPD, ARDS diagnosed by expert physician The use of positive inotropic drugs, such as dopamine and dobutamine Severe cardiovascular and pulmonary failure High intracranial pressure Having a score (-1 to 4+) based on Richmond's Scale Having blood coagulation disorder and thrombocytopenia
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **35**
More than 1 sample in each individual
Number of samples in each individual: **4**
Each patient will undergo a tracheal suctioning for 4 times.
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
35 patients with single-group mechanical ventilation each will be suctioned in 4 times with different catheter sizes and negative pressure.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of yasuj University of Medical Sciences
Street address
Assistance of Research and Technology of the University , Yasouj University of Medical Sciences , Shahid Motahari Blvd., Yasuj , Iran
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Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Approval date
2019-02-16, 1397/11/27
Ethics committee reference number
IR.YUMS.REC.1397.143

Health conditions studied

1

Description of health condition studied
Coma, unspecified
ICD-10 code
R40.20
ICD-10 code description
Unspecified coma

Primary outcomes

1

Description
Hemodynamic parameters
Timepoint
Immediately before - immediately - 10 and 20 minutes after the trachea suction
Method of measurement
Central Monitor device

2

Description

Respiratory parameters

Timepoint

Immediately before, immediately, 10 and 20 minutes after the trachea suction

Method of measurement

Ventilator machine and computational formula

Secondary outcomes

1

Description

Heart rate

Timepoint

Immediately before , immediately , 10 and 20 minutes after the trachea suction

Method of measurement

central Monitor device

2

Description

فشار خون سیستول

Timepoint

Immediately before - immediately - 10 and 20 minutes after the trachea suction

Method of measurement

Central Monitor device

3

Description

Diastolic blood pressure

Timepoint

Immediately before - immediately - 10 and 20 minutes after the trachea suction

Method of measurement

Central Monitor device

4

Description

Median arterial pressure

Timepoint

Immediately before - immediately - 10 and 20 minutes after the trachea suction

Method of measurement

Central Monitor device

5

Description

Arterial oxygen saturation

Timepoint

Immediately before - immediately - 10 and 20 minutes after the trachea suction

Method of measurement

Central Monitor device

6

Description

Airway resistance

Timepoint

Immediately before ,immediately ,10 and 20 minutes after the trachea suction

Method of measurement

Computational formula

7

Description

Dynamic compilation

Timepoint

Immediately before ,immediately ,10 and 20 minutes after the trachea suction

Method of measurement

Computational formula

8

Description

Maximum airway pressure

Timepoint

Immediately before ,immediately ,10 and 20 minutes after the trachea suction

Method of measurement

Ventilator Bennet 840

9

Description

Plato Press

Timepoint

Immediately before , immediately , 10 and 20 minutes after the trachea suction

Method of measurement

Ventilator Bennet 840

10

Description

Expiratory tidal volume

Timepoint

Immediately before ,immediately , 10 and 20 minutes after the trachea suction

Method of measurement

Ventilator Bennet 840

Intervention groups

1

Description

Intervention group: Intervention on 35 patients by single-group method Which will have a tracheal tube under mechanical ventilation Each patient is subjected to suction for 4 times, initially with a catheter of 10 and a negative pressure of 100 For the second time, a catheter of 10 and a negative pressure of 150 For the third time, a catheter of 12 and a negative pressure of 100 and for the fourth time the catheter size 12 and the negative pressure 150 are used and the interval between two suction tracheal suction doses for each patient is at least 2 hours.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Sajjad Hospital - Shahid Beheshti Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yasouj 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
Yasouj University of Medical Sciences

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Position
Ph.D. Pediatric Nursing

Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
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