

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3323 4115

##### Email address

salarimo@yums.ac.ir

##### 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

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Assistance of Research and Technology of the University , Yasouj University of Medical Sciences , Shahid Motahari Blvd., Yasuj , Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**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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nursing school , Dr. Shahid Jalil street, Yasouj , Iran

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Vice-chancellor of Research, Dr. Hossein Mari Oryad

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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

**Full name of responsible person**

Dr. Mohsen Salari

**Position**

Ph.D. Pediatric Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Maryam Jafari

**Position**

Master's candidate in medical- surgical Nursing

**Latest degree**

Master

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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