

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison the effect of two levels of negative pressure in open endotracheal tube suction on physiological indices among patients in intensive care units of Al-Zahra Hospital, Isfahan in 2013

#### Protocol summary

##### Summary

Comparison the effect of two levels of negative pressure in open endotracheal tube suction on physiological indices among patients in intensive care units of Al-Zahra Hospital, Isfahan in 2013, Study design: Randomized clinical trial with parallel design, Study population: patients admitted to the intensive care unit at Al-Zahra Hospital, Major inclusion criteria: minimum age 18 years and maximum age 75 years, having endotracheal tube and connect to ventilator, no coagulation disorders and thrombocytopenia, having stable hemodynamics before suctioning (SBP > 100, HR < 120, MAP > 70) and no hypoxemia (SPO<sub>2</sub> < 90). Major inclusion criteria: age over than 18; obtaining informed consent; no blood clotting disorders; no chronic respiratory disease; intubation time between 48 hours and one week. Major exclusion criteria: extubation during the study; become unstable hemodynamic parameters such as bradycardia, arrhythmia, cyanosis, loss of arterial oxygen. sample size: 60, Intervention or interventions: First group suctioned with negative pressure of 100 mmHg and second group with 200 mmHg. Time of intervention: suction with negative pressure 100 and 200 mmHg will be performed for each group and Design variables will be taken immediately before, during, 5 and 20 minutes after endotracheal suctioning in both groups. Primary outcomes: changes in physiological indices

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013041713039N1**  
Registration date: **2013-07-26, 1392/05/04**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-26, 1392/05/04

##### Registrant information

###### Name

Hojatollah Yousefi

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7543

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-04-11, 1392/01/22

##### Expected recruitment end date

2013-05-24, 1392/03/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of two levels of negative pressure in open endotracheal tube suction on physiological indices among patients in intensive care units of Al-Zahra Hospital, Isfahan in 2013

##### Public title

Comparison the effect of two levels of negative pressure in open endotracheal tube suction on physiological indices among patients in intensive care units of Al-Zahra Hospital, Isfahan in 2013

#### **Purpose**

Supportive

#### **Inclusion/Exclusion criteria**

Major inclusion criteria: age over than 18; obtaining informed consent; no blood clotting disorders; no chronic respiratory disease; intubation time between 48 hours and one week. Major exclusion criteria: extubation during the study; become unstable hemodynamic parameters such as bradycardia, arrhythmia, cyanosis, loss of arterial oxygen

#### **Age**

From **18 years** old to **75 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Isfahan University of Medical sciences

##### **Street address**

Isfahan University of Medical Sciences, Azadi Square, Hezar-Jerib Street, Isfahan. Postal cod: 81746-73461

##### **City**

Isfahan

##### **Postal code**

81746-73461

#### **Approval date**

2013-04-09, 1392/01/20

#### **Ethics committee reference number**

392012

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Respiratory conditions due to other specified external agents

#### **ICD-10 code**

J70.8

#### **ICD-10 code description**

Respiratory conditions due to other specified external agents

## **Primary outcomes**

### **1**

#### **Description**

Spo2

#### **Timepoint**

Immediately before, During, 5 and 20 min after endotracheal suctioning

#### **Method of measurement**

Vital signs monitor

## **Secondary outcomes**

### **1**

#### **Description**

Heart Rate

#### **Timepoint**

Immediately before, During, 5 and 20 min after endotracheal suctioning

#### **Method of measurement**

Vital signs monitor

### **2**

#### **Description**

MAP

#### **Timepoint**

Immediately before, During, 5 and 20 min after endotracheal suctioning

#### **Method of measurement**

Vital signs monitor

### **3**

#### **Description**

SBP

#### **Timepoint**

Immediately before, During, 5 and 20 min after endotracheal suctioning

#### **Method of measurement**

Vital signs monitor

### **4**

#### **Description**

DBP

#### **Timepoint**

Immediately before, During, 5 and 20 min after endotracheal suctioning

**Method of measurement**

Vital signs monitor

**5**

**Description**

Respiratory Rate(RR)

**Timepoint**

Immediately before, 5 and 20 min after endotracheal suctioning

**Method of measurement**

Vital signs monitor

**Intervention groups**

**1**

**Description**

this study is a parallel study that First group suctioned with negative pressure of 100 mmHg with standard method

**Category**

Prevention

**2**

**Description**

Scnd group suctioned with negative pressure of 200 mmHg with standard method

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Al-Zahra Hospital, Intensive Care Units

**Full name of responsible person**

Jahanbakhsh Vahdatnejad (student of MSc in critical care nursing)

**Street address**

Al-Zahra Hospital, Sofeh Avenue, Isfahan. Postal cod: 81746-75731

**City**

Isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Peiman Adibi

**Street address**

Isfahan University of Medical Sciences, Azadi Square,

Hezar-Jerib street, Isfahan. Postal cod: 81746-73461

**City**

Isfahan

**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, Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Jahanbakhsh Vahdatnejad

**Position**

student of MSc in critical care nursing

**Other areas of specialty/work**

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PHD

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Isfahan University of Medical Sciences

**Full name of responsible person**

Jahanbakhsh Vahdatnejad

**Position**

student of MSc in critical care nursing

**Other areas of specialty/work**

**Street address**

Faculty of Nursing and Midwifery, Isfahan University  
of Medical Sciences, Azadi Square, Hezar-Jerib

**City**

**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*