

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Investigating and comparing the effects of open and closed tracheal suction system on the pain and respiratory indicators in patients under mechanical ventilation in intensive care units

#### Protocol summary

##### Study aim

Investigating and comparing the effects of open and closed tracheal suction system on the pain in patients under mechanical ventilation in intensive care units

##### Design

Clinical trial with intervention group (closed suction) and control group (open suction), single-blind due to statistics analyst, random allocation

##### Settings and conduct

Closed suction for the intervention group and open suction for the control group are performed by the researcher based on the patients' needs and according to the 2014 suction protocol in Intensive Care Units of Al-Zahra Hospital in Isfahan. Before suctioning, in order to access the patient's basic information, respiratory and pain indicators are recorded at three twenty minute intervals, and the mean is considered as the patient's basic status. Respiratory indicators are recorded in the special form by the researcher's colleague before, 10 minutes after and 30 minutes after the suction; similarly, pain indicators are recorded before, during, 10 minutes and 30 minutes after the suction. This study is single-blind due to statistics analyst blinding.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients undergoing volumetric mechanical ventilation; hospitalized in ICU with no suction contraindication and zero or -1 RASS; Exclusion criteria: patients who face with hemodynamic dysfunction or life threatening conditions.

##### Intervention groups

All patients with inclusion criteria will be divided into two groups of closed suction and open suction using Minimization software. In the closed suction or intervention group, closed suctioning and in the open suction or control group, open suctioning are performed.

##### Main outcome variables

Respiratory and pain indicators

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180108038267N1**

Registration date: **2018-02-23, 1396/12/04**

Registration timing: **retrospective**

Last update: **2018-02-23, 1396/12/04**

Update count: **0**

##### Registration date

2018-02-23, 1396/12/04

##### Registrant information

##### Name

somayeh ghafari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7517

##### Email address

somayeghafari@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2018-01-21, 1396/11/01

##### Actual recruitment start date

2017-04-21, 1396/02/01

##### Actual recruitment end date

2017-12-22, 1396/10/01

##### Trial completion date

empty

## Scientific title

Investigating and comparing the effects of open and closed tracheal suction system on the pain and respiratory indicators in patients under mechanical ventilation in intensive care units

## Public title

comparing two close suction and open suction method in patients under mechanical ventilation in intensive care units

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

admission to the ICU of the hospital Being at the age of 18-70 years no history of cardiac diseases no primary pulmonary pathophysiology ventilation with Synchronized Intermittent Mandatory Ventilation (SIMV) Positive End Expiratory Ventilation (PEEP)=3-5 cm H2O Tidal Volume(TV)=8 - 10 ml/kg Fractional Inspired Oxygen(FIO2)=40% to 60% Pressure Support Ventilation (PSV)=8 -10 cm no coagulation disorder or thrombocytopenia Richmond Agitation Sedation Scale (RASS) =0,-1

### Exclusion criteria:

hemodynamic instability (in systolic blood pressure (SBP) less and greater than 20 mmHg and in diastolic blood pressure (DBP) less and greater than 20 mmHg) having cardiac arrhythmia

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **70**

Actual sample size reached: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients eligible for the research will be selected by simple method and then, using Minimization software, are divided into two open and closed suction groups. This software, based on the variables of sex, age, BMI, and spo2, divides the patients into two open and closed suction groups in such a way that the groups have the least difference.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Open and closed suction are performed by the researcher and the data is recorded by the researcher's colleague who is one personnel of ICU and, hence, the researcher is not aware of the recorded data.

## 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, Hezar Jarib street, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2016-02-21, 1394/12/02

#### Ethics committee reference number

IR.MUI.REC.1394.3.976

## Health conditions studied

### 1

#### Description of health condition studied

patients under mechanical ventilation in intensive care units

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Patient's level of pain

#### Timepoint

Before the suction, during the suction, ten minutes and thirty minutes after the suction.

#### Method of measurement

CPOT scale

### 2

#### Description

Respiratory indicators

#### Timepoint

Before the suction, ten minutes and thirty minutes after the suction

#### Method of measurement

Monitoring of patient-ventilator

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For the intervention group, closed suction is performed while the patient is connected to a mechanical ventilator due to the need of patient, by the researcher according to the 2014 protocol. Respiratory Indicators including respiratory rate, arterial oxygen saturation, minute ventilation, static and dynamic compliance and pain recorded by monitoring and pain assessment tool are registered in the data collection form by a researcher before, 10 minutes and thirty minutes after suctioning.

#### Category

Treatment - Devices

### 2

#### Description

Control group: The open suction is done by removing the patient from the ventilator by the researcher according to the 2014 protocol. Respiratory Indicators including respiratory rate, arterial oxygen saturation, minute ventilation, static and dynamic compliance and pain recorded by monitoring and pain assessment tool are registered in the data collection form by a researcher before, 10 minutes and thirty minutes after suctioning.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra hospital

##### Full name of responsible person

Fariba Taleghani

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Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Fatemeh Khaier

##### Position

Critical Care Nursing Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

### Contact

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Esfahan University of Medical Sciences  
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Associate professor  
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## Person responsible for updating data

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**Name of organization / entity**  
Esfahan University of Medical Sciences  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No plan has been considered yet to publish the results. There is no further information.

### 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