

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

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7544

Fax

+98 31 3669 9398

Email

ftmkhaier@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fariba Taleghani

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7544

Fax

+98 31 3669 9398

Email

ftmkhaier@gmail.com

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

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7544

Email

ftmkhaier@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Somayeh Ghafari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7544

Email

somayehghafari@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Somayeh Ghafari

Position

Associate professor in nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7544

Email

somayehghafari@nm.mui.ac.ir

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