

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparing two levels of closed system suction pressure in ICU patients: Evaluating the relative safety of higher values of suction pressure

Protocol summary

Study aim

This study was designed to evaluate the effects on gas exchange and suctioning volume of two levels of suctioning pressure in closed suctioning system.

Design

Clinical trial, two Intervention groups with cross over design, double blinded, randomized with computer based minimization software

Settings and conduct

50 adult ICU patients are studied. The study involves consecutive application of two different suction pressures of 100 and 200 mmHg to each patient. To make the carry over effect as low as possible, the order of applying suction pressure are randomly chosen for each subject. Assignment of subjects to each group and setting the suction pressure for each round of suctioning are carried out by the second researcher in position, who is not participated in the act of suctioning and data measurements. Chief researcher, who performs the suctioning procedure, is blinded regarding the level of suction pressure and patient's assigned group.

Participants/Inclusion and exclusion criteria

ICU patients, older than 18 years, undergoing mechanical ventilation, using volume modes, 24 hours after intubation time, with orotracheal intubation and no severe hypoxemia ($SpO_2 < 85\%$, $PaO_2 < 50$ mmHg), and stable hemodynamic condition ($MAP > 70$ mmHg, $HR < 130/min$) will enter to this study. Patients with hemodynamic instability ($DBP > 100$ mmHg, \uparrow or \downarrow 20 mmHg in SBP, $SpO_2 < 85\%$ and \uparrow 20 b/min in HR) and those requiring suctioning in wash out period, and when the patient's family are unwilling to enter and continue the research do not enter to the study.

Intervention groups

Intervention groups are divided into two groups, first AB and BA second group. Patients in AB group receive 100 mmHg suction pressures first, and then 200 mmHg after two hours of washout period. BA group receive reverse order.

Main outcome variables

SpO_2 , heart rate and suctioning volume are recorded before, 1, 3 and 20 minutes after suctioning.

General information

Reason for update

Acronym

suction pressure . closed suctioning system

IRCT registration information

IRCT registration number: **IRCT20160924029930N2**

Registration date: **2018-07-20, 1397/04/29**

Registration timing: **retrospective**

Last update: **2018-07-20, 1397/04/29**

Update count: **0**

Registration date

2018-07-20, 1397/04/29

Registrant information

Name

somayeh haghghat borujeni

Name of organization / entity

Isfahan University of medical Science

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Recruitment status

Recruitment complete

Funding source

isfahan university of medical science

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2010-08-30, 1389/06/08

Actual recruitment start date

2010-05-22, 1389/03/01

Actual recruitment end date

2010-08-30, 1389/06/08

Trial completion date

empty

Scientific title

Comparing two levels of closed system suction pressure in ICU patients: Evaluating the relative safety of higher values of suction pressure

Public title

Comparing two levels of closed system suction pressure in ICU patients: Evaluating the relative safety of higher values of suction pressure

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

patients older than 18 years hospitalized in ICU undergoing mechanical ventilation using volume modes 24 hour after intubation time with orotracheal intubation with no severe hypoxemia (SpO₂ < 85%, PaO₂ < 50 mmHg) stable hemodynamic condition (MAP > 70 mmHg, HR < 130/min)

Exclusion criteria:

Patients with hemodynamic instability (DBP > 100 mmHg, ↑ or ↓ 20 mmHg in SBP, SpO₂ < 85% and ↑ 20 b/min in HR) those requiring suctioning in wash out period when the patient or patient's family was unwilling to participate and continue the research

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

We use a minimization model. we can minimize the differences between two groups (AB, BA) and at the same time to enroll subjects randomly into groups, hence eliminating selection bias and the predictability of subject assignment. To further decrease the carry over effect, we incorporate a wash-out period of two hours between two episodes of suctioning. Minimization factors included age, gender, base SpO₂, admission diagnosis, ventilator mode, and length of ICU stay.

Blinding (investigator's opinion)

Double blinded

Blinding description

Chief researcher, who performed the suctioning procedure, was blinded regarding the level of suction pressure and patient's assigned group. Assignment of subjects to each group and setting the suction pressure for each round of suctioning were carried out by the second researcher in position, who was not participated in the act of suctioning and data measurements. Patients were also blinded regarding the level of suction pressure.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Isfahan University of Medical Science

Street address

Isfahan. Hezar Jarib Avn. Isfahan University of Medical Science, Faculty of Nursing and Midwifery

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Postal code

8873137186

Approval date

2011-07-18, 1390/04/27

Ethics committee reference number

390126

Health conditions studied**1****Description of health condition studied**

Oxygenation of patient under endotracheal suctioning with closed suctioning system

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

SPO₂

Timepoint

before, 1,3 and 20 min after suctioning

Method of measurement

measures from pulseoximetry

Secondary outcomes

1

Description

Heart rate and hemodynamic instability

Timepoint

before, during and 20 min after suctioning

Method of measurement

measures from heart monitoring

2

Description

secretion volume in endotracheal suctioning

Timepoint

after each suctioning

Method of measurement

graded container attached to bottle of suction device

Intervention groups

1

Description

Intervention group 1: Two consecutive ten seconds closed suctioning system using suction pressures of 100 at first and then 200 mmHg will do with 2 hour washout period between each suctioning.

Category

Treatment - Other

2

Description

Intervention group 2: Two consecutive ten seconds closed suctioning system using suction pressures of 200 at first and then 100 mmHg will do with 2 hour washout period between each suctioning.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Somayeh Haghighat Borujeni

Street address

Hakim Nezami Avenue, Alzahra Hospital, Nursing and Midwifery Department, Isfahan University of Medical Sciences, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Somayeh Haghighat Borujeni

Position

Senior Lecture, Faculty member

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data on patients' information and their
outcomes can be shared.

When the data will become available and for how long

Access start has no limits.

To whom data/document is available

Academic and scientific researchers

Under which criteria data/document could be used

Possibility and determination of access to data and
analyzes is allowed after obtaining permission from the
university's research and technology vice president.

From where data/document is obtainable

Research department, Faculty of Nursing and Midwifery,
Isfahan University of Medical Sciences, Isfahan, Iran, Tell
00983137927533

What processes are involved for a request to access data/document

Submitting a written request regarding the cause of the
need for access to the documentation of the research
and the introduction of the applicant to the Vice-
Chancellor of Research of the Faculty of Nursing and
Midwifery of Isfahan

Comments