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 tow levels of suctioning pressure in close suctioning system.

Design

Clinical trial, tow Intervention groups with cross over design, double blinded, randomized with computer base minimization software

Settings and conduct

50 adult ICU patients are studied. The study involve 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 performe 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 hour after intubation time, with orotracheal intubation and no sever hypoxemia (SpO2 < 85%, PaO2 < 50 mmHg),and stable hemodynamic condition (MAP > 70 mmHg,HR < 130/min) will enter to this study. Patients with hemodynamic instability (DBP > 100 mmHg, ↑ or ↓ 20 mmHg in SBP, SpO 2 < 85% and ↑ 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 tow hour of washout period. BA group receive reverse order.

Main outcome variables

SpO2, 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

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somayeh haghighat 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 sever hypoxemia (SpO2 < 85%, PaO2 < 50 mmHg) stable hemodynamic condition (MAP > 70 mmHg,HR < 130/min)
Exclusion criteria:
Patients wit hemodynamic instability (DBP > 100 mmHg, ↑ or ↓ 20 mmHg in SBP, SpO 2 < 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
City
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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 pulseoximetery

Secondary outcomes

1

Description
Heart rate and hemodynamic instability
Timepoint
befor, 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
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Sponsors / Funding sources

1

Sponsor
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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
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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