Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of endotracheal suction using two methods, endotracheal N-acetylcysteine and normal saline, on hemodynamic parameters and arterial blood gases in intubated patients under mechanical

Protocol summary

Study aim
Comparison of the effect of Endotracheal suction on hemodynamic parameters and arterial blood gases in two methods of endotracheal N-acetylcysteine and normal saline in intubated patients under mechanical ventilation

Design
Clinical trial with a control group, with factorial groups, single blind, randomized, phase 3 on 90 patients. A lottery method is used for randomization.

Settings and conduct
The location of the study is the intensive care units of Amir al-Mominin Ali Hospital, Zabul City. The study is a single-blind study of the type of participants. way to do: At first, 5 minutes before the start of endotracheal suction, an arterial blood sample is taken from all patients. Before intratracheal suction, hemodynamic parameters are controlled. immediately after recording the hemodynamic parameters, the endotracheal suction procedure is performed. 25 minutes after endotracheal suction, arterial blood samples are taken from patients again, and hemodynamic parameters are controlled at intervals of 1, 5 and 30 minutes after endotracheal suction.

Participants/Inclusion and exclusion criteria
Inclusion criteria: intubated patients under mechanical ventilation and stable hemodynamic conditions Exclusion criteria: lack of intubation and unstable hemodynamic conditions of patients

Intervention groups
Endotracheal suction with 1- With normal saline: Endotracheal inoculation of 3 ml of normal saline serum 2- With N-acetyl cysteine: Endotracheal inoculation of 2 ml of N-acetyl cysteine 20% 3- Without solution inoculation: Endotracheal suction is performed routinely without solution inoculation.

Main outcome variables
Arterial blood gases include pH, Saturation of Peripheral Oxygen, relative pressure of carbon dioxide, relative pressure and bicarbonate level. Hemodynamic parameters include heart rate, respiration rate, blood pressure and arterial saturation.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231104059949N1**
Registration date: **2023-12-14, 1402/09/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-14, 1402/09/23**
Update count: **0**

Registration date
2023-12-14, 1402/09/23

Registrant information
Name
Ahmad Absalan
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2024-07-21, 1403/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of endotracheal suction using two methods, endotracheal N-acetylcysteine and normal saline, on hemodynamic parameters and arterial blood gases in intubated patients under mechanical

Public title

Comparison of the effect of endotracheal suction using two methods, endotracheal N-acetylcysteine and normal saline, on hemodynamic parameters and arterial blood gases in intubated patients under mechanical

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are connected to mechanical ventilation for at least 48 hours and at most one week Patients with endotracheal tubes Patients who are between 20 and 60 years old Patients who are hemodynamically stable (heart rate between 60-100 beats per minute, blood pressure between 160/100-110/60 mmHg, Spo2 more than 90%, urinary output more than 30 ml/hour) Patients with normal electrolyte levels and no cardiac arrhythmia Insensitivity to N-acetylcysteine and other drugs Absence of pulmonary edema, chronic obstructive pulmonary diseases and asthma Patients who do not have chest trauma or chest tube Absence of brain edema, spinal cord injury, increased intracranial pressure

Exclusion criteria:

Patients who are hemodynamically unstable (heart rate less than 60 beats per minute, blood pressure less than 100/60 mmHg, Spo2 less than 90%) Any changes in mechanical ventilation settings during the study Death of the patient Lack of consent of the patient's family Use of muscle relaxants and inotropic drugs during the study

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

By simple randomization method using lottery First, three study groups are randomly assigned. Then, the code is written to the total number of the sample volume, and to allocate the samples for groups 1, 2, 3, each specified code is allocated by lottery.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the patients are not aware of the treatment group due to the decreased level of consciousness and are kept blind. After the patient meets the conditions for entering the study, informed consent is obtained from the first-degree family members of the patient, but they do not know about the type of intervention that has been performed.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zabul University of Medical Sciences

Street address

University of Medical Sciences, Rajaei St., Zabul City

City

Zabul

Province

Sistan-va-Balouchestan

Postal code

98616615881

Approval date

2023-10-11, 1402/07/19

Ethics committee reference number

IR.ZBMU.REC.1402.087

Health conditions studied

1

Description of health condition studied

Patients should be intubated and under mechanical ventilation.

ICD-10 code

Z99.11

ICD-10 code description

Dependence on respirator [ventilator] status

Primary outcomes

1

Description

Heart rate, which is considered as a hemodynamic parameter.

Timepoint
The heart rate is measured at the beginning of the study (before the intervention) and 1, 5 and 30 minutes after the intervention.
Method of measurement
It is controlled and recorded by means of monitoring connected to the patient.

2

Description
Blood pressure, which is considered as a hemodynamic parameter.
Timepoint
The blood pressure is measured at the beginning of the study (before the intervention) and 1, 5 and 30 minutes after the intervention.
Method of measurement
It is controlled and recorded by means of monitoring connected to the patient.

3

Description
Arterial oxygen saturation, which is considered as a hemodynamic parameter.
Timepoint
The Arterial oxygen saturation is measured at the beginning of the study (before the intervention) and 1, 5 and 30 minutes after the intervention.
Method of measurement
It is controlled and recorded by means of monitoring connected to the patient.

4

Description
Respiratory rate, which is considered as a hemodynamic parameter.
Timepoint
The Respiratory rate is measured at the beginning of the study (before the intervention) and 1, 5 and 30 minutes after the intervention.
Method of measurement
For 1 minute, the Respiratory rate is counted and recorded in the patient's chest by observation method.

5

Description
Arterial blood gases include PH, PCO2, PO2, HCO3, SPO2.
Timepoint
Arterial blood gases are measured at the beginning of the study (5 minutes before the intervention) and 25 minutes after the intervention.
Method of measurement
Blood gas Technomedica Arterial Blood Gas Analyzer Gastat-720 series

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Endotracheal suction with N-acetylcysteine is such that 2 ml of 20% N-acetyl cysteine liquid solution is poured by the researcher into the patient's tracheal tube during suction and it is suctioned immediately.
Category
Rehabilitation

2

Description
Intervention group: Endotracheal suction with normal saline is done in such a way that 3 ml of sterile normal saline serum is poured by the researcher into the patient's tracheal tube during suctioning and it is suctioned immediately.
Category
Rehabilitation

3

Description
Control group: Endotracheal suction without inoculating solution
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir al Mominin Ali Hospital
Full name of responsible person
Ahmad Absalan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Dr. Hadi Mirzaei

Street address
Central Headquarters of the University of Medical Sciences, Shahid Bagheri St.,Jahad Square., Zabul City

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https://zbmu.ac.ir/fa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zabol 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
Zabol University of Medical Sciences

Full name of responsible person
Ahmad Absalan

Position
MSc student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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