

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of adding acetazolamide to routine regimen on respiratory parameters of mechanically ventilated patients in the intensive care unit

Protocol summary

Study aim

The effect of acetazolamide on respiratory parameters of patients connected to a ventilator in intensive care unit

Design

This study is conducted as a clinical trial with a control group and an intervention group, in a triple-blind manner, with random allocation through block randomization method, phase 3 on 30 patients.

Settings and conduct

This study is performed in the ICU of Shahid Yahya Nejad Hospital in Babol. Neither patients nor staff are aware of the type of intervention, and both groups receive routine care. The researcher will measure respiratory parameters in both groups half an hour before and 2 hours after taking acetazolamide.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients should be connected to a ventilator; Patients diagnosed with non-traumatic diseases (absence of trauma, especially trauma to the head and chest). Age over 18 years old (adults).
Exclusion criteria: Hemodynamic instability (patients during heart shock and severe cardiovascular disorders, patients with brain death, patients in need of pacemakers, patients with renal failure, etc.); Having metabolic acidosis in the ABG test.

Intervention groups

Intervention group: Patients will receive acetazolamide in addition to routine care. Control group: they will receive only routine care.

Main outcome variables

Respiratory rate, Tidal volume, Percentage of hemoglobin with oxygen (SPO2)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210707051809N1**

Registration date: **2022-07-18, 1401/04/27**

Registration timing: **prospective**

Last update: **2022-07-18, 1401/04/27**

Update count: **0**

Registration date

2022-07-18, 1401/04/27

Registrant information

Name

behnam esbakian bandpey

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3272 2788

Email address

behnam.esbakian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of adding acetazolamide to routine regimen on respiratory parameters of mechanically

ventilated patients in the intensive care unit

Public title

The effect of acetazolamide on respiratory parameters of mechanically ventilated patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should be connected to a ventilator Patients diagnosed with non-traumatic illness (absence of trauma, especially head and chest trauma) Age over 18 years old

Exclusion criteria:

Hemodynamic instability (patients during heart shock and severe cardiovascular disorders, patients with brain death, patients in need of pacemakers, patients with renal failure, etc.) Presence of metabolic acidosis in the ABG test

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The study samples will be randomly assigned to two intervention and control groups (blocked) using the two-way block method, which will be the intervention group (A) and the control group (B). AA, BB, BA, AB state will be created and these states will be written on separate cards, and the doctor will take out the patient card from the bag randomly for fifteen separate times and will write these states in order. For example, if the first card is AB, it means that the first patient is part of the intervention group and the second patient is in the control group, and sampling is done randomly until the states are finished.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the patients and the clinical caregivers and the data analyzer are not aware of the study method

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences; Ganj Afrooz Street

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2021-07-09, 1400/04/18

Ethics committee reference number

IR.MUBABOL.REC.1400.094

Health conditions studied

1

Description of health condition studied

Patients connected to a ventilator

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Respiratory rate

Timepoint

Four times a day (morning, once before and once after) - (evening, once before and once after) and for 3 consecutive days

Method of measurement

Cardiopulmonary monitoring device and ventilator device

2

Description

Tidal volume

Timepoint

Four times a day (morning, once before and once after) - (evening, once before and once after) and for 3 consecutive days

Method of measurement

Cardiopulmonary monitoring device and ventilator device

3

Description

Percentage of hemoglobin saturated with oxygen

Timepoint

Four times a day (morning, once before and once after) - (evening, once before and once after) and for 3

consecutive days
Method of measurement
Cardiopulmonary monitoring device and ventilator device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients connected to a ventilator who, in addition to routine care, take acetazolamide tablets. Acetazolamide 250 mg tablets are administered orally (gavage) twice daily for 3 consecutive days.

Category

Treatment - Drugs

2

Description

Control group: Patients connected to a ventilator who receive only routine care and do not take acetazolamide tablets

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahya Nejad Hospital of Babol

Full name of responsible person

Behnam Esbakian Bandpey

Street address

Yahya Nejad Hospital; Mostafa Khomeini Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol 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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Behnam Esbakian Bandpey

Position

Instructor of Paramedical School

Latest degree

Master

Other areas of specialty/work

Medical Education

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After the end of the study and data analysis, the results and data, including the study protocol, statistical analysis map, clinical study report, after removing the confidential information, will be available to all people who want to access and use this study.

When the data will become available and for how long

2023

To whom data/document is available

Everyone

Under which criteria data/document could be used

Access is free

From where data/document is obtainable

behnam.esbakian@gmail.com

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

Send email

Comments