

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of synchronized intermittent mandatory ventilation and pressure-regulated volume control on the rate of asynchrony in mechanically ventilated patients

Protocol summary

Study aim

To compare the effect of synchronized intermittent mandatory ventilation with pressure-regulated volume control on the rate of asynchrony in mechanically ventilated patients

Design

Phase III assessor-blind randomized placebo-controlled trial with parallel groups on 100 patients, randomization performed using a randomization table generated by the Random Allocation software

Settings and conduct

This study will be performed on 100 multiple trauma patients admitted to the ICU of Bandar Abbas Shahid Mohammadi Hospital. Patients will be randomized into two groups based on a randomization table. In intervention group 1 patients will receive synchronized intermittent mandatory ventilation with a respiratory rate of 10-15/min, tidal volume of 6 mg/kg, positive end-expiratory pressure of 5-7, pressure support of 10, and trigger sensitivity of 2-3 L and in the intervention group 2 patients will receive the pressure-regulated volume control (PRVC) mode of the ventilator. The rate of asynchrony will be evaluated by an individual unaware of patient grouping from the monitor and graph of the ventilator within 72 hours; therefore, the study will be assessor-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 15-70 years, mechanical ventilation, multiple trauma Exclusion criteria: Hemodynamic instability, pneumothorax, pneumomediastinum

Intervention groups

Intervention group 1: Synchronized intermittent mandatory ventilation with a respiratory rate of 10-15/min, tidal volume of 6 mg/kg, positive end-expiratory pressure of 5-7, pressure support of 10, and trigger sensitivity of 2-3 L Intervention group 2: The

pressure-regulated volume control mode of the ventilator

Main outcome variables

Rate of asynchrony

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230702058640N1**

Registration date: **2023-07-04, 1402/04/13**

Registration timing: **prospective**

Last update: **2023-07-04, 1402/04/13**

Update count: **0**

Registration date

2023-07-04, 1402/04/13

Registrant information

Name

Amirreza Talebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 5009

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of synchronized intermittent mandatory ventilation and pressure-regulated volume control on the rate of asynchrony in mechanically ventilated patients

Public title

Rate of asynchrony in mechanically ventilated patients with synchronized intermittent mandatory ventilation versus pressure-regulated volume control on the

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 15-70 years Mechanical ventilation Multiple trauma

Exclusion criteria:

Hemodynamic instability Pneumothorax
Pneumomediastinum

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into two groups using simple randomization with individuals as the unit of randomization and a randomization table produced by the Random Allocation software. An individual uninformed in the study will write A or B on a card and put it in an opaque envelope. Then the associated number in the randomization table will be written on the back of the envelope. One envelope will be allocated to each patient in order of entrance to the study. Allocation concealment will be done using opaque envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The rate of asynchrony will be recorded by an individual unaware of the mode of the ventilator based on the ventilator graph and monitor; therefore, the study will be assessor-blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Approval date**

empty

Ethics committee reference number**2****Ethics committee****Name of ethics committee**

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Faculty of Medicine, across from Kargaran Sports Complex, Imam Hossein Blvd., Bandar Abbas, Iran

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2023-05-20, 1402/02/30

Ethics committee reference number

IR.HUMS.REC.1402.054

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

Mechanical ventilation

ICD-10 code

Z51.8

ICD-10 code description

Encounter for other specified aftercare

Primary outcomes**1****Description**

Rate of asynchrony

Timepoint

Within 72 hours of the intervention initiation

Method of measurement

Observation of early cycling, delayed cycling, ineffective triggering, and double triggering on the monitor of graph of the ventilator

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Synchronized intermittent mandatory ventilation with a respiratory rate of 10-15/min, tidal volume of 6 mg/kg, positive end-expiratory pressure of 5-7, pressure support of 10, and trigger sensitivity of 2-3 L

Category

Prevention

2

Description

Intervention group: The pressure-regulated volume control mode of the ventilator

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Amirreza Talebi

Street address

Shahid Mohammadi Hospital, Jomhuri Eslami Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research Hormozgan University
of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

Street address

across from Kargaran Sports Complex, Imam Hossein
Blvd., Bandar Abbas, Hormozgan, Iran

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teaghamolaei@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellery for Research Hormozgan 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Amirreza Talebi

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available