

# 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

matin.talebi12@gmail.com

##### 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.,  
Bandar Abbas, Hormozgan, Iran

##### City

Bandar Abbas

##### Province

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##### Postal code

9791991551

##### Phone

+98 76 3334 7000

##### Email

shmh@hums.ac.ir

##### Web page address

<https://shmh.hums.ac.ir/>

## 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

##### City

Bandar Abbas

##### Province

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##### Postal code

7919693116

##### Phone

+98 76 3371 0393

##### Email

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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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Amirreza Talebi  
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**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Amirreza Talebi  
**Position**  
Intern  
**Latest degree**  
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**Other areas of specialty/work**

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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