

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### **A comparison between the impacts of the synchronized intermittent mandatory ventilation and minimum minute ventilation on physiological and hemodynamic parameters in patients admitted to the intensive care unite**

#### **Protocol summary**

##### **Study aim**

Determination of the effect of synchronized intermittent mechanical ventilation and minimum minute ventilation modes on the physiological and hemodynamic parameters of patients admitted to the intensive care unit Determine the effect on vital signs, Medium arterial pressure and arterial blood gases

##### **Design**

This is an experimental cross-over clinical trial. The subjects were permuted block randomly assigned to two groups of control (45) and intervention (45). At first, one of the ventilation Modes is used in the first group and other ventilation mode in the second group, and after 6 hours, ventilation modes in the groups are changed, and the results of the analysis of arterial blood gases and the physiological parameters of the patient will be recorded on the checklist.

##### **Settings and conduct**

The site of the study is the Sabzevar Shahid Beheshti Emdad Hospital. Minimum minute ventilation and synchronized intermittent mechanical ventilation are used intersecting in two groups for 6 hours and In the end, the effects of ventilation modes are measured

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: Patients under mechanical ventilation admitted to the special department, Age between 18 and 60 years, Stable hemodynamic Inclusion criteria :Symptoms of respiratory distress , Dysrhythmia during research, Unstable hemodynamic , Patients who can not be used minimum minute ventilation and synchronized intermittent mechanical ventilation as directed by the doctor, Chest trauma, Lung and diaphragm damage

##### **Intervention groups**

Minimum minute ventilation modes and synchronized intermittent mechanical ventilation are used Intersecting in groups for 6 hours, At the end of each period, the

effect of any ventilation mode is measured on the physiological and hemodynamic parameters

##### **Main outcome variables**

Improvement of physiological and hemodynamic parameters

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20180515039669N1**

Registration date: **2018-07-14, 1397/04/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-14, 1397/04/23**

Update count: **0**

##### **Registration date**

2018-07-14, 1397/04/23

##### **Registrant information**

##### **Name**

Mahdi Ghorbanpour

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 51 4464 3794

##### **Email address**

ems@medsab.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2018-06-05, 1397/03/15

**Expected recruitment end date**

2018-09-06, 1397/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparison between the impacts of the synchronized intermittent mandatory ventilation and minimum minute ventilation on physiological and hemodynamic parameters in patients admitted to the intensive care unite

**Public title**

Comparison between the impacts of synchronized intermittent mandatory ventilation and minimum minute ventilation in patients admitted to the intensive care unite

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient under mechanical ventilation admitted to the intensive care unit Patients aged 18-60 years Stable hemodynamic (mean arterial pressure greater than 70 mm Hg)

**Exclusion criteria:**

Symptoms of respiratory distress and oxygenation and ventilation disorders Dysrhythmia during research Unstable hemodynamic (mean arterial pressure less than 70 mm Hg) Patients who can not use the Synchronized intermittent mechanical ventilation and Minimum minute ventilation modes as directed by the physician Chest trauma Lung and diaphragm damage

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Permuted block randomization

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Sabzevar University of Medical Sciences

**Street address**

No. 3, Abureyhan6, North Abureyhan,

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

96176

**Approval date**

2018-05-09, 1397/02/19

**Ethics committee reference number**

1397.002.IR.MEDSAB.REC

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

All patients have trauma except severe chest and lung trauma

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Vital signs

**Timepoint**

At the beginning of the study, 15 minutes, 1 hour and 6 hours after the study

**Method of measurement**

Monitoring device

**2****Description**

Arterial blood gases

**Timepoint**

At the beginning of the study, 15 minutes, 1 hour and 6 hours after the study

**Method of measurement**

Arterial blood gas analyzer

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: At first, applying the minimum minute ventilation mode for 6 hours and measuring and recording the physiological (vital signs and mean arterial pressure) and hemodynamics (arterial blood gases) parameters, and then changing the mode to synchronized intermittent mechanical ventilation mode for 6 hours, record the measured values as before and then compare the results with each other

#### Category

Treatment - Other

### 2

#### Description

Control group: Apply the synchronized intermittent mechanical ventilation mode initially for 6 hours and measure and record the physiological (vital signs and mean arterial pressure) and hemodynamic parameters (arterial blood gases) and then modify this mode to minimum minute ventilation mode for 6 hours, record the measured values as before and then compare the results with each other

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid beheshti emdad hospital

##### Full name of responsible person

Mahdi ghorbanpour

##### Street address

No. 3, Abu Rihan 6, North Abu Rihan

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ems@medsab.ac.ir

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<http://www.medsab.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Dr. Fereshteh Gharat

##### Street address

Sabzevar University of Medical Sciences, Kosar St, Tawhid Township.

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913112

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+98 51 4401 8319

##### Email

ems@medsab.ac.ir

##### Web page address

<http://www.medsab.ac.ir/index.aspx?siteid=1&pageid=2085>

##### Grant name

Dr. Fereshteh Gharat

##### Grant code / Reference number

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

Yes

##### Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mahdi Ghorbanpour

##### Position

Nurse

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

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No. 3, Abu Rihan 6, North Abu Rihan.

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##### Province

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<http://www.medsab.ac>.

## Person responsible for scientific inquiries

### Contact

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Sabzevar University of Medical Sciences  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
Mahdi Ghorbanpour

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Nurse  
**Latest degree**  
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**Other areas of specialty/work**  
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**Web page address**  
<http://www.medsab.ac.ir/index.aspx?fkeyid=&siteid=1&pageid=2262>

## 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

No more 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