

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of magnesium sulfate on hemodynamic and respiratory parameters of multiple trauma patients under mechanical ventilation

#### Protocol summary

##### Study aim

To evaluate the effect of magnesium sulfate on hemodynamic and respiratory parameters of multiple trauma patients under mechanical ventilation

##### Design

Phase III single-blind (assessor-blind) randomized controlled trial with parallel groups on 104 patients, randomization performed using a randomization table generated by the Random Allocation software

##### Settings and conduct

This study will include 104 multiple trauma patients under mechanical ventilation in Shahid Mohammadi Hospital intensive care unit, Bandar Abbas. Patients will be randomized into two groups. Patients in the intervention group will receive 2 g magnesium sulfate 20% in daily serum within the first 24 hours and those in the control group will only receive daily serum. Blood pressure, heart rate, oxygen saturation, pulmonary compliance, and airway resistance will be assessed every 6 hours and arterial blood gas every 12 hours by an individual blinded to the patient grouping (assessor-blind). Mechanical ventilation will be under volume control mode with 6 L tidal volume, 10-14/min respiratory rate, 40-50% fraction of inspired oxygen, positive end-respiratory pressure of 5, and pressure support of 10. Also, all patients will receive 50-100 mcg/h fentanyl and 1-2 mg/h midazolam.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: multiple trauma, mechanical ventilation, admission to the intensive care unit within 24 hours of trauma, age 18-70 years Exclusion criteria: history of pulmonary disease such as asthma and chronic obstructive pulmonary disease, pulmonary contusion, pneumothorax, cardiovascular instability

##### Intervention groups

Intervention group: 2 g magnesium sulfate 20% in daily serum within the first 24 hours Control group: Only daily serum within the first 24 hours

##### Main outcome variables

Blood pressure, oxygen saturation (SpO<sub>2</sub>), heart rate, pulmonary compliance, airway resistance, arterial blood gas

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230719058853N1**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

##### Registration date

2023-08-12, 1402/05/21

##### Registrant information

##### Name

Sarina Charani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3334 7000

##### Email address

sarinach9678@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2024-02-20, 1402/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of magnesium sulfate on hemodynamic and respiratory parameters of multiple trauma patients under mechanical ventilation

**Public title**  
The effect of magnesium sulfate on the heart and respiration of multiple trauma patients under mechanical ventilation

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Multiple trauma Mechanical ventilation Admission to the intensive care unit within 24 hours of trauma Age 18-70 years  
**Exclusion criteria:**  
History of pulmonary diseases such as asthma and chronic obstructive pulmonary disease Pulmonary contusion Pneumothorax Cardiovascular instability

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: **104**

**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 uninvolved 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 individual responsible for the assessment of hemodynamic and respiratory parameters will be unaware of patient grouping, while given the nature of the intervention and that there is no placebo, the patient and those related to the patient will not be blinded. Therefore, the study will be single-blind with blinding the assessor.

**Placebo**  
Not used

**Assignment**  
Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### 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.

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7916613885

#### Approval date

2023-07-30, 1402/05/08

#### Ethics committee reference number

IR.HUMS.REC.1402.211

## Health conditions studied

### 1

#### Description of health condition studied

Multiple trauma

#### ICD-10 code

T07

#### ICD-10 code description

Unspecified multiple injuries

## Primary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Every 6 hours within the first 24 hours

#### Method of measurement

The monitoring device of the intensive care unit

### 2

#### Description

Oxygen saturation

#### Timepoint

Every 6 hours within the first 24 hours

#### Method of measurement

Pulse oximeter

## Secondary outcomes

## 1

### **Description**

Heart rate

### **Timepoint**

Every 6 hours within the first 24 hours

### **Method of measurement**

The monitoring device of the intensive care unit

## 2

### **Description**

Pulmonary compliance

### **Timepoint**

Every 6 hours within the first 24 hours

### **Method of measurement**

The ventilator device

## 3

### **Description**

Airway resistance

### **Timepoint**

Every 6 hours within the first 24 hours

### **Method of measurement**

The ventilator device

## 4

### **Description**

Arterial blood gas

### **Timepoint**

Every 12 hours within the first 24 hours

### **Method of measurement**

Arterial blood gas measurement in arterial blood sample

## **Intervention groups**

## 1

### **Description**

Intervention group: 2 g magnesium sulfate 20% (Shahid Ghazi Co., Tabriz, Iran) in daily serum within 24 hours

### **Category**

Prevention

## 2

### **Description**

Control group: Only daily serum within the first 24 hours

### **Category**

Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Shahid Mohammadi Hospital

#### **Full name of responsible person**

Sarina Charani

#### **Street address**

Shahid Mohammadi Hospital, Jomhuri Eslami Blvd.,  
Hormozgan, Iran

#### **City**

Bandar Abbas

#### **Province**

Hormozgan

#### **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**

Faculty of Medicine, Across from Kargaran Sports  
Complex, Imam Hossein Blvd.

#### **City**

Bandar Abbas

#### **Province**

Hormozgan

#### **Postal code**

7919693116

#### **Phone**

+98 76 3371 0393

#### **Email**

teaghamolaei@gmail.com

#### **Web page address**

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

### **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**

Sarina Charani

**Position**

Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Shahid Mohammadi Hospital, Jomhuri Eslami Blvd.,  
Bandar Abbas, Hormozgan, Iran

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

9791991551

**Phone**

+98 76 3334 7000

**Fax****Email**

sarinach9678@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Sarina Charani

**Position**

Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Shahid Mohammadi Hospital, Jomhuri Eslami Blvd.,  
Bandar Abbas, Hormozgan, Iran

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

9791991551

**Phone**

+98 76 3334 7000

**Fax****Email**

sarinach9678@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Sarina Charani

**Position**

Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Shahid Mohammadi Hospital, Jomhuri Eslami Blvd.,  
Bandar Abbas, Hormozgan, Iran

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

9791991551

**Phone**

+98 76 3334 7000

**Fax****Email**

sarinach9678@yahoo.com

## 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