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 (SpO2), 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, Jomhouri 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

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Person responsible for updating data

Contact

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Fax

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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