Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 2026

Comparison of two methods of administering magnesium through continuous infusion (۲۴ hours) and short-term infusion (۴ hours) in the correction of hypomagnesemia in patients admitted to the ICU of Sina Hospital: a clinical pilot study

Protocol summary

Study aim
Investigating the hypomagnesemia treatment protocol in patients hospitalized in ICU and comparing the efficacy of two methods of continuous infusion and intermitent infusion.

Design
The randomized clinical trial , non-blind, double-arm and parallel. After confirming hypomagnesemia using the magnesium challenge test, patients will be divided into two groups using the randomization method through permuted blocks of 6 created by the software. This is a pilot study and will be conducted on 30 patients (15 patients in each group).

Settings and conduct
Patients hospitalized in the ICU of Sinai Hospital, if meet the inclusion criteria, magnesium challenge test is first performed to ensure the identification of hypomagnesemia (If the patient has magnesium deficiency, magnesium retention is more than 50%.). patients divided using the randomization method through blocks of 6; one group received magnesium sulfate for 24hour continuous infusion for 3 days, and other received magnesium sulfate in the form of a 4-hour short infusion for 3 days. washing out in fourth day, then a magnesium challenge test is performed and 24-hour urine is collected. Retention of magnesium is more than 50%, considered no treatment.

Participants/Inclusion and exclusion criteria
patients age over 18 years, who have been hospitalized for less than 96 hours in the ICU and filled out written consent, will be included. If the serum concentration of magnesium is higher than 4 mg/dl, CKD , the 2nd and 3rd degrees heart block, muscle weakness , refractory shock، survival is less than 48 hours, will be excluded

Intervention groups
the first group of received magnesium sulfate as a continuous infusion over 24 hours and for 3 days and the second group receive magnesium sulfate as a 4-hour short infusion for 3 days.

Main outcome variables
Investigating the hypomagnesemia treatment protocol in patients hospitalized in ICU

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200322046833N4**
Registration date: **2024-01-05, 1402/10/15**
Registration timing: **prospective**

Last update: **2024-01-05, 1402/10/15**
Update count: **0**

Registration date
2024-01-05, 1402/10/15

Registrant information

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Farhad Najmeddin

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 6695 4709

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of administering magnesium through continuous infusion (۲۴ hours) and short-term infusion (۴ hours) in the correction of hypomagnesemia in patients admitted to the ICU of Sina Hospital: a clinical pilot study

Public title

Comparison of two methods of administering magnesium through continuous infusion (۲۴ hours) and short-term infusion (۴ hours) in the correction of hypomagnesemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hypomagnesemia patients hospitalized in the intensive care unit Less than 96 hours have passed since ICU admission. written consent to enter the study

Exclusion criteria:

Magnesium serum concentration higher than 4 mg/dl Stage IV, V CKD based on the Cockcroft-Gault formula heart rate less than 50 times per minute, 2nd and 3rd degree heart block receiving a high dose of furosemide (more than 3 mg/hr) The need to receive magnesium outside the protocol History of muscle weakness disease (MS, Guillain-Barre, botulism, myasthenia gravis) Refractory shock (EP و NEP > ۳۰ mcg/min) survival less than 48 hours Patients with AKI massive blood transfusion unable to take a urine sample for any reason

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the randomization method, patients are divided into two groups 1:1 ratio, by the randomization table. The permuted block randomization table is generated electronically in block sizes of six. In order to randomize, 5 blocks with 6 column are created, the number of each group in the blocks is equal and randomly, if the patients have the conditions to enter the study, they will be placed in one of the groups in the order of the rows of the block.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sina Hospital - Tehran University of Medical Sciences

Street address

Sina Hospital, Imam Khomeini St, Hasanabad Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2023-11-16, 1402/08/25

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1402.104

Health conditions studied

1

Description of health condition studied

hypomagnesemia

ICD-10 code

E83.4

ICD-10 code description

Disorders of magnesium metabolism

Primary outcomes

1

Description

The number of patients who have more than 50% magnesium retention at the end of the study.

Timepoint

Urine collection 24 hours after magnesium administration.

Method of measurement

24-hour urine collection and examination of magnesium excreted in 24-hour urine

Secondary outcomes

1

Description
Change in the percentage of urinary magnesium excreted compared to the baseline condition.
Timepoint
Measurement of urine magnesium before starting treatment and after finishing treatment
Method of measurement
Measurement of urine magnesium after 24hour

Intervention groups

1

Description
Intervention group: Correction of the patient's hypomagnesemia by administering continuous infusion of magnesium sulfate (7.5 gram magnesium sulfate manufactured by Daro Pakhsh industry) during 24 hours and for 3 days
Category
Treatment - Drugs

2

Description
Intervention group: Correction of the patient's hypomagnesemia by administering magnesium sulfate (7.5 gram magnesium sulfate manufactured by Daro Pakhsh industry) during a 4-hour infusion for 3 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Farhad Najmeddin
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Sina hospital, Hassan-abad square, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbari Sari
Street address
Sina hospital, Hassan-abad square, Tehran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Farhad Najmeddin
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Clinical results will be published through an original article and All other data will be available on request

When the data will become available and for how long
Up to 5 years after publishing the clinical results

To whom data/document is available
Researchers and ethics committee

Under which criteria data/document could be used
Ethical evaluation and review articles without financial conflicts of interest.

From where data/document is obtainable
Responsible Researcher Dr farhadnajmeddin by the following email f-najmeddin@tums.ac.ir

What processes are involved for a request to access data/document
Data will be available within 2 weeks after the email check. The email should include the Conflict of interest disclosure

Comments