Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of magnesium sulfate on lactate clearance in sepsis

Protocol summary

Study aim

Evaluation of the correlation between serum magnesium level and lactate clearance at acute phase of sepsis
Evaluation of the correlation between intracellular magnesium level and lactate clearance at acute phase of sepsis

Design

This is a randomized, placebo-controlled and blinded clinical trial. Fifty adult patients with diagnosis of sepsis will equally be assigned to magnesium or placebo group according permuted block randomization method.

Settings and conduct

Critically ill adult patients with diagnosis of sepsis who admitted to general ICU of Imam Khomeini Hospital will be evaluated for eligibility. Fifty patients will equally be assigned to magnesium or placebo group. Patients in the magnesium group will receive magnesium sulfate as intravenous infusion to attain serum magnesium level near to 3 mg/dl. Patients in the placebo group will receive the same volume of saline. Duration of intervention is 72 hours. Medication and placebo have same packaging and appearance.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Critically ill adult patients (18-65) admitted to ICU with diagnosis of sepsis will be recruited.
Exclusion criteria: Patients with hypermagnesemia [Mg]> 3.5 mg/dL, hypomagnesemia [Mg] <1.5 mg/dL, renal failure (GFR <30 ml/min /1.73 m2), moderate to severe hepatic insufficiency (child pugh score B, C), seizure , chronic alcohol consumption, malignancy, MAP <65 mm Hg resistant to vasopressors, diabetic ketoacidosis and pregnant women will be excluded.

Intervention groups

Magnesium group: Patients in this group will receive magnesium sulfate as intravenous infusion to attain serum magnesium level of 3 mg/dl as the study goal.
Control group: Patients in this group will receive placebo.

Main outcome variables

Evaluation of the effect of magnesium supplementation on lactate clearance in critically ill patients with sepsis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180410039254N1**
Registration date: **2018-07-11, 1397/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-11, 1397/04/20**
Update count: **0**

Registration date

2018-07-11, 1397/04/20

Registrant information

Name

Afsaneh Noormandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6617 7540

Email address

a-noormandipoor@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of magnesium sulfate on lactate clearance in sepsis

Public title
Effect of magnesium sulfate on blood infection

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Critically ill adult patients (18-65 years old) admitted to ICU with diagnosis of sepsis will be included.

Exclusion criteria:
Exclusion criteria: Patients with hypermagnesemia (serum magnesium level> 3.5 mg/dL, hypomagnesemia (serum magnesium level<1.5 mg/dL), renal failure (GFR <30 ml/min /1.73 m2), moderate to severe hepatic insufficiency (child pugh score B, C), seizure , chronic alcohol consumption, malignancy, MAP <65 mm Hg resistant to vasopressors, diabetic ketoacidosis and pregnant women will be excluded.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Permuted block randomization Unit of randomization: 4 patients in each block Randomization tool: SAS statistical software, secured envelope How to create a random sequence: SAS statistical software Allocation concealment: Sequentially numbered, sealed, opaque envelopes

Blinding (investigator's opinion)
Triple blinded

Blinding description
Medication and placebo are individually coded and only one patient's non-responsible nurse is aware of the codes. The medication and placebo do not differ in appearance or mode and duration of injection.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical sciences

Street address
Ghods Ave. Tehran University of Medical Sciences, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
-

Approval date
2018-04-10, 1397/01/21

Ethics committee reference number
IR.TUMS.TIPS.REC.1397.037

Health conditions studied

1

Description of health condition studied
Sepsis

ICD-10 code
A41.50

ICD-10 code description
Gram-negative sepsis, unspecified

Primary outcomes

1

Description
Lactate clearance

Timepoint
At the beginning of the study (before the intervention) and then every 6 hours on the day 0 - Day 1 - Day 2

Method of measurement
By spectrophotometry and Pars-Azmoon kit in mg/dl

2

Description
Serum magnesium level

Timepoint
At the beginning of the study (before the intervention) and then every 6 hours on the day 0 - Day 1 - Day 2

Method of measurement
By spectrophotometry and Pars-Azmoon kit in mg/dl

3

Description

Intracellular magnesium concentration (RBC magnesium level)

Timepoint

At the beginning of the study (before the intervention) and then every 6 hours on the day 0 - Day 1 - Day 2

Method of measurement

By spectrophotometry and Pars-Azmoon kit in mg/dl

Secondary outcomes

1

Description

SOFA score (Sepsis-related organ failure assessment score)

Timepoint

At the beginning of the study (before the intervention), then daily on day 0 - day 1- day 2

Method of measurement

Based on the SOFA score scale

2

Description

APACHE II score (Acute Physiologic And Chronic Health Evaluation)

Timepoint

At the beginning of the study (before the intervention), then daily on day 0 - day 1- day 2

Method of measurement

Based on the APACHE-II score scale

3

Description

Duration of intensive care unit stay

Timepoint

Daily

Method of measurement

Count the number of hospitalization days in the intensive care unit

4

Description

Mortality

Timepoint

Daily

Method of measurement

Count the number of dead patients

Intervention groups

1

Description

Intervention group: 25 patients will be received magnesium sulfate (2 g magnesium sulfate in 50 ml of normal saline over one hour) as intravenous infusion. Infusion of magnesium sulfate will be continued to maintain serum magnesium level near 3 mg /dl for 72 hours of acute phase of sepsis.

Category

Treatment - Drugs

2

Description

Control group: 25 patients will be received 50 mL normal saline over 1 hour intravenous infusion. The rate and volume of normal serum infusion will be similar to that of the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Hossein Khalili

Street address

Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6119 2756

Email

khalilih@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

02166706141

Phone

+98 21 8898 7381

Email

msahrai@sina.tums.ac.ir

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
Hossein Khalili
Position
Pharm.D, PHD
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
-
Phone
+98 21 6658 1598
Fax
Email
khalilih@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hossein Khalili
Position
Pharm.D, PHD
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
-
Phone
+98 21 6658 1598
Fax
Email
khalilih@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hossein Khalili
Position
Pharm.D, PHD
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
-
Phone
+98 21 6658 1598
Fax
Email
khalilih@tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Results of the study will be published. The study protocol and statistical analysis will be included in the

manuscript.

When the data will become available and for how long

One year after end of the study, data will be published and will be available in databases.

To whom data/document is available

After permission form the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes.

Under which criteria data/document could be used

Other researchers are permitted to included the results in their systematic reviews and meta-analysis.

From where data/document is obtainable

Contact scientific responsible person for the clinical trial as needed.

What processes are involved for a request to access data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks.

Comments

Data sharing is according to permission from the sponsor.