Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of magnesium sulfate efficacy in reducing sedative requirement in patients under mechanical ventilation

Protocol summary

Study aim
Evaluation of magnesium sulfate efficacy in reducing sedative requirement in patients under mechanical ventilation

Design
This is a double-blinded, randomized clinical trial. Eligible patients will be assigned to one of the groups of the study according the permuted block randomization.

Settings and conduct
This double-blind randomized clinical trial is designed in Imam Khomeini Hospital Complex. Patients in the ICU requiring mechanical ventilation support for more than 48 hours will include. Sedation of patients will be done based on the protocol. The amount of sedative drugs required for each patient is determined based on the Richmond Agitation Sedation Scale (RASS) tool. Patients in addition to designed sedation protocol, will receive magnesium sulfate or placebo. The study duration is 48hours.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult patients in ICU who need mechanical ventilation support for at least 48 hours
Exclusion criteria: History of allergic reactions to magnesium sulfate or chronic renal failure

Intervention groups
Control group: In addition to the sedation protocol, patients will be treated with placebo (saline).
Intervention group: In addition to the sedation protocol, patients will receive intravenous infusion of magnesium sulfate. The target serum level of magnesium in this group is 3mg/dL. The dose of magnesium for each patient will be based on the rule of thumb. The one third of the calculated dose will be infused as a bolus within 30 minutes and the rest within 24 hours.

Main outcome variables
24 and 48 hours cumulative dose of intravenous opioid

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100228003449N33**
Registration date: **2024-12-11, 1403/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-11, 1403/09/21**
Update count: **0**

Registration date
2024-12-11, 1403/09/21

Registrant information

Name
Hossein Khalili

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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khalilih@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-01, 1403/09/11

Expected recruitment end date
2025-06-01, 1404/03/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of magnesium sulfate efficacy in reducing sedative requirement in patients under mechanical ventilation

Public title
Magnesium sulfate and reducing sedative requirement

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients in ICU who required mechanical ventilation for at least 48 hours

Exclusion criteria:
Patients with a history of allergic reactions to intravenous magnesium sulfate Patients who need deep sedation (RASS≥-4) Patients with any brain damage Patients with myasthenia gravis Patients with chronic renal failure (eGFR less than 30 ml/min) Pregnant and lactating women

Age
From **18 years** old to **80 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: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by the method of random blocks. According to the sample size, four patients are included in each block. Random groups are AABB, BBAA, ABBA, ABAB, BABA, BAAB. Random numbers will be generated by Excel software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Intravenous magnesium sulfate and saline will be prepared and labeled by a technician not involved in the study. The patient and research members are unaware of the contents of the syringes.

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
1417614411

Approval date
2024-10-27, 1403/08/06

Ethics committee reference number
IR.TUMS.TIPS.REC.1403.143

Health conditions studied

1

Description of health condition studied
Management of pain, agitation/sedation and delirium in mechanically ventilated patients

ICD-10 code
F13

ICD-10 code description
Sedative, hypnotic, or anxiolytic related disorders

Primary outcomes

1

Description
Cumulative dose of required intravenous opioid

Timepoint
At the end of 24 and 48 hours

Method of measurement
Based on fentanyl dose or equivalent dose of other registered opioids

Secondary outcomes

1

Description
Required adjuvant sedative drugs

Timepoint
At the end of 24 and 48 hours

Method of measurement
Based on the registered drug and cumulative dosage

2

Description
Required analgesic drugs

Timepoint
At the end of 24 and 48 hours
Method of measurement
Based on the registered drug and cumulative dosage

3

Description
Duration of respiratory support
Timepoint
Daily
Method of measurement
Patient follow-up

4

Description
Duration of ICU stay
Timepoint
Daily
Method of measurement
Patient follow-up

5

Description
28-day mortality
Timepoint
28 days after starting the intervention
Method of measurement
Patient follow-up

6

Description
Safety of intravenous magnesium sulfate
Timepoint
Continuous monitoring during the study period
Method of measurement
Patient follow-up

7

Description
Change in serum CRP level
Timepoint
48 hours after starting the intervention
Method of measurement
Laboratory data

Intervention groups

1

Description
Control group: In addition to the sedation protocol, patients will receive placebo (saline).
Category
Placebo

2

Description
Intervention group: In addition to the sedation protocol, patients will receive intravenous magnesium sulfate. The target serum level of magnesium in this group is 3 mg/dL. The dose of magnesium for each patient will be calculated based on the rule of thumb. According to this rule, every 1 gram of magnesium sulfate leads to an increase of 0.18 mg/dL in the serum level of magnesium. One third of the calculated dose will be infused as a bolus within 30 minutes and the rest within 24 hours. Each 1 gram of intravenous magnesium sulfate will be diluted in 50 ml of normal saline and infused at least within 1 hour.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Hossein Khalili
Street address
Keshavarz Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave, Tehran, Iran
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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
Hossein Khalili
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
The results of the study will be published as an article. The study protocol and statistical analyzes used in the

article will be included.

When the data will become available and for how long

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

To whom data/document is available

After permission from 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

For this you may ask Hossein Khalili through following information: Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran Postal code: 1417614411- E-mail: khalilih@tums.ac.ir

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 sponsor within 2 weeks.

Comments