Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effects of Magnesium Sulfate Injection at Doses of 2 and 4 Grams on Ventricular Response Control in Patients with Atrial Fibrillation (AF)

Protocol summary

Study aim
Evaluation of the effect of intravenous magnesium sulfate injection at doses of 2 and 4 grams on ventricular rate control in patients with acute atrial fibrillation.

Design
Randomized, double-blind, placebo-controlled parallel-group phase 3 clinical trial on 90 patients. Block randomization method with block size of six using SPSS software was used for randomization.

Settings and conduct
Patients with acute atrial fibrillation presenting to the emergency department of Imam Khomeini Hospital in Ardabil city who meet the eligibility criteria will be enrolled in the study and will be randomly allocated to three groups using block randomization method with block size of six. This study will be performed as double-blind in which the patients, treating physician, and data analyst will not be informed about the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years, acute atrial fibrillation, heart rate greater than 120 beats per minute, informed consent Exclusion criteria: Severe renal failure, severe heart failure, systolic blood pressure less than 90, bradycardia, hypersensitivity to magnesium sulfate, intravenous magnesium within past 24 hours

Intervention groups
Intervention group 1: Intravenous injection of 50% magnesium sulfate at a dose of 2 grams, manufactured by Sinagen Pharmaceutical Company, as a single dose via slow injection over 5-10 minutes; Intervention group 2: Intravenous injection of 50% magnesium sulfate at a dose of 4 grams, manufactured by Sinagen Pharmaceutical Company, as a single dose via slow injection over 10-15 minutes; Control group: Intravenous injection of 100 mL placebo (0.9% normal saline, manufactured by Sinagen), single dose, slow injection over 10-15 minutes

Main outcome variables
Heart rate less than 90 beats per minute at 4 hours after injection; percentage of heart rate reduction at 4 hours after injection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260509069313N1**
Registration date: **2026-06-22, 1405/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-22, 1405/04/01**
Update count: **0**

Registration date
2026-06-22, 1405/04/01

Registrant information

Name
farnaz Mohammadrezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 45 3325 1401

Email address
dr.farnazrezae@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2026-09-21, 1405/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effects of Magnesium Sulfate Injection at Doses of 2 and 4 Grams on Ventricular Response Control in Patients with Atrial Fibrillation (AF)

Public title
Effect of magnesium sulfate in atrial fibrillation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients (over 18 years old) with acute atrial fibrillation and a heart rate greater than 120 beats per minute (bpm) Willingness to participate in the study and informed consent
Exclusion criteria:
Severe renal failure (GFR less than 30) Severe heart failure (Class IV based on NYHA) Systolic blood pressure less than 90 mmHg Bradycardia (heart rate less than 50 beats per minute) Known hypersensitivity to magnesium sulfate Intravenous magnesium administration within the past 24 hours Serum magnesium level greater than 2.5 mg/dL
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is block randomization with block sizes of six. Since there are 3 study groups, each block of 6 patients is randomly allocated such that 2 patients are assigned to each group per block. The unit of randomization is individual. Stratified randomization is performed based on age (less than 65 years and 65 years or older) and gender. The randomization tool is SPSS statistical software version 26 using the random number generation function. The random sequence is generated by a statistician who has no role in patient treatment. Allocation of patients to intervention groups is performed using sealed, opaque, sequentially numbered envelopes. The envelopes are opened by a person independent of the principal investigator.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding Method: This study was conducted as a double-blind randomized clinical trial. The blinding process was implemented as follows: Blinding of Participants: To ensure patients remained blinded, the interventions (different doses of Magnesium Sulfate or Normal Saline as a placebo) were prepared in 50cc syringes that were identical in appearance, color, and volume. Therefore, the participants were unaware of the specific treatment they received. Blinding of Investigators and Outcome Assessors: The random allocation sequence was kept in sealed envelopes. A designated nurse, who was not involved in outcome assessment or data recording, opened the envelopes and prepared the syringes according to the assigned codes. The principal investigator and the person responsible for measuring heart rate and recording clinical outcomes remained blinded to the group assignments and the contents of the syringes throughout the data collection period.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Ardabil University of Medical Sciences
Street address
Administrative Complex of Ardabil University of Medical Sciences, University Ave., Ardabil, Iran.
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹۸۵۹۹۱
Approval date
2026-04-12, 1405/01/23
Ethics committee reference number
IR.ARUMS.REC.1405.023

Health conditions studied

1

Description of health condition studied
Atrial Fibrillation
ICD-10 code
I48
ICD-10 code description
Atrial fibrillation and flutter

Primary outcomes

1

Description
Percentage of patients whose heart rate reaches less than 90 beats per minute at 4 hours after injection
Timepoint
Before intervention, 4 hours after injection
Method of measurement
Using cardiac monitoring and electrocardiogram recording

2

Description
Percentage of heart rate reduction from baseline at 4 hours after injection
Timepoint
Before intervention, 4 hours after injection
Method of measurement
Calculation of percentage of heart rate reduction compared to baseline using cardiac monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Intravenous injection of magnesium sulfate at a dose of 2 grams. The medication is magnesium sulfate with concentration of 50% (500 mg/mL) manufactured by Sinagen Pharmaceutical Company. The dose is 2 grams as a single dose. The route of administration is slow intravenous injection over 5-10 minutes.
Category
Treatment - Drugs

2

Description
Intervention group 2: Intravenous injection of magnesium sulfate at a dose of 4 grams. The medication is magnesium sulfate with concentration of 50% (500 mg/mL) manufactured by Sinagen Pharmaceutical Company. The dose is 4 grams as a single dose. The route of administration is slow intravenous injection over 10-15 minutes.
Category
Treatment - Drugs

3

Description
Control group: Intravenous injection of placebo (100 mL of 0.9% normal saline - sodium chloride 0.9%) manufactured by Sinagen Pharmaceutical Company. The dose is 100 mL as a single dose. The route of administration is slow intravenous injection over 10-15 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Educational and Medical Center
Full name of responsible person
Dr. Zahra Amirajam
Street address
Imam Khomeini Educational and Medical Center, Shahid Ghafour Jaddi St., Azadegan Ave., Ardabil, Iran.
City
Ardabil
Province
Ardabil
Postal code
5618985991
Phone
+98 914 139 6066
Email
amirajamzahra@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Mohsen Arzanlou
Street address
Administrative Complex of Ardabil University of Medical Sciences, University Ave., Ardabil, Iran.
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹۸۵۹۹۱
Phone
+98 45 3353 4790
Email
arzanlo53@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Zahra Amirajam
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Administrative Complex of Ardabil University of Medical Sciences, University Ave., Ardabil, Iran.
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹۸۵۹۹۱
Phone
+98 45 3353 4790
Email
zahra.amirajam@arums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Zahra Amirajam
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Administrative Complex of Ardabil University of Medical Sciences, University Ave., Ardabil, Iran.
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹۸۵۹۹۱
Phone
+98 45 3353 4790
Email
zahra.amirajam@arums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Farnaz Mohammadrezaei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
18 meter Azadeghan, Ghafour Jedi Blvd, Imam khomeini Hospital
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹۸۵۹۹۱
Phone
+98 45 3325 1401
Fax
Email
dr.farnazrezae@gmail.com

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
All data is potentially sharable once individuals are de-identified.
When the data will become available and for how long
The data access period will begin 6 months after the publication of the final results.
To whom data/document is available
The data will be available to researchers working in academic, scientific, and research institutions.
Under which criteria data/document could be used
The data will be shared for the purpose of meta-analyses and secondary analyses. Access is subject to the submission and approval of a formal research proposal by the corresponding author and the signing of a data use agreement to ensure confidentiality.
From where data/document is obtainable
Requests for access to data should be sent to the

corresponding author via email. Data will be available to researchers in academic institutions starting 6 months after publication for the purpose of secondary analysis or meta-analysis, provided that a formal research proposal is submitted and approved.

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

The process for requesting data: Applicants must submit a formal request, including a research proposal and the objectives of the analysis, to the corresponding author's email. The request will be reviewed by the research team. Upon approval, a Non-Disclosure Agreement (NDA) will be sent to the applicant. After the signed agreement is returned, the de-identified data will be shared via email or a secure file-sharing platform.

Comments