Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparing the prophylactic effect of adding magnesium to Metoral in reducing atrial fibrillation after coronary artery bypass graft surgery

Protocol summary

Study aim

Determining the prophylactic effect of adding magnesium to Metoral in reducing atrial fibrillation after coronary artery bypass graft (AF post CABG) in patients who are candidates for coronary artery bypass graft (CABG).

Design

This study is a randomized controlled clinical trial on 102 elective CABG patients. In this study, 102 patients will be divided into 2 groups (group 1 including magnesium + metoral, group 2 metoral alone).

Settings and conduct

Patients are admitted to Amirul Mominin Hospital from the day before the operation. Patients will be randomly assigned to 2 groups (magnesium + Metoral and Metoral only), also the drugs used will be prepared by the anesthesiologist (consultant professor) in syringes of equal volume with the same shape and appearance and then at the specialist's disposal. Anesthesia is responsible for injecting drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria -CABG candidate patients between 35-75 - are operated with that pump. -With informed consent -The average duration of surgery is 7 hours - There is no heart valve repair surgery along with CABG - ASAⅢ,Ⅳ patients -Not allergic to Metoral-Magnesium - have acid-base disorders resistant to treatment before surgery Exit criteria -suffer cardio-respiratory arrest during surgery. -do not agree to continue -need valve repair during surgery. -after the induction of anesthesia, the surgeon decides to perform surgery with the pump OFF. -have acid-base disorders resistant to treatment

Intervention groups

The first group (Metoral + magnesium) (1-3 mg⁄kg/hour) put Metoral on the syringe pump, which is infused for 30 minutes, and at the same time, 2 grams of magnesium will be slowly injected for the patients. The second group (Metoral) 1-3 mg⁄kg per hour will be infused for 24 hours.

Main outcome variables

The occurrence of atrial fibrillation or other arrhythmias after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240527061915N1**
Registration date: **2024-07-08, 1403/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-08, 1403/04/18**
Update count: **0**

Registration date

2024-07-08, 1403/04/18

Registrant information

Name

malihe safari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

m.safari@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2024-12-20, 1403/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the prophylactic effect of adding magnesium to Metoral in reducing atrial fibrillation after coronary artery bypass graft surgery

Public title
The prophylactic effect of adding magnesium to metoral in reducing coronary AF

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All CABG candidate patients referred to Amirul Mominin Arak Hospital All patients candidates for elective operations The age of patients between 35-75 years All patients are candidates for CABG only All patients who are operated with that pump All patients with informed consent to participate in this study The average duration of surgery is maximum 7 hours All patients who do not have heart valve repair surgery with CABG ASAⅢ,Ⅳ patients Patients who are not allergic to Metoral-Magnesium All patients who have acid-base disorders resistant to treatment before surgery

Exclusion criteria:
Patients who suffer cardio-respiratory arrest during surgery Patients who do not agree to continue the study or cooperate All CABG candidate patients who require valve repair during surgery All patients who, after the induction of anesthesia, the surgeon decides to perform surgery with the pump OFF All patients who have acid-base disorders resistant to treatment before surgery

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, CABG candidate patients referred to Amirulmomenin Hospital who meet the inclusion criteria and will be electively subjected to open heart surgery will be divided into two equal groups of magnesium + Metoral and Metoral. In this study, permutation random block method will be used for randomization. For this purpose, blocks of 6 will be used. In each block, the letter M (Metoral) is written on three cards and the letter S (Magnesium Sulfat) is written on three cards. Some of the selected random blocks of 6 are as follows: SMSMMS, SSMSMM, MSSMMS, SMSMSM, MSSMMS, MSMMSS, SMMMSS, MSSMMS, SMMSSM, SSMSMM. (For example, the method of random allocation in a block of 6 SMSMMS is as follows: the first patient to treatment S, the second patient to treatment M, the third patient to treatment S, the fourth patient to treatment M, the fifth patient to treatment M and the sixth patient to treatment S are allocated by accident.

Blinding (investigator's opinion)
Double blinded

Blinding description
The aforementioned study is a double-blind study in which CABG candidate patients who meet the inclusion criteria are included in the study after obtaining informed consent, but it does not matter which of the study groups (Metoral and Metoral + magnesium) they are in. They don't know. Also, the mentioned drugs in 2 groups will be prepared by the anesthesiologist (design consultant) in the same shape, size and volume, and labels 1 and 2 will be placed on them. Then the said syringes will be given to the anesthesiologist in charge of the plan, who does not know the type of groups, to be injected to the patients. Also, the intern in charge of the project, who is responsible for the questionnaires of the project, and the data analyst, do not know about the studied groups, so the study will be double-blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Sardasht, Basij Square, University Complex of the Great Prophet (PBUH), Arak

City
Arak

Province
Markazi

Postal code
3848176341

Approval date
2024-05-05, 1403/02/16

Ethics committee reference number
IR.ARAKMU.REC.1403.045

Health conditions studied

1

Description of health condition studied
All CABG candidate patients referred to Amirul Mominin Hospital
ICD-10 code
T82
ICD-10 code description
Complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description
Occurrence of atrial fibrillation or other arrhythmias after surgery
Timepoint
72 hours after the operation
Method of measurement
Monitoring and examination of patients will be used in open heart ICU

Secondary outcomes

1

Description
Mortality and morbidity rate of patients
Timepoint
72 hours after the operation
Method of measurement
Monitoring and examination of patients in open heart ICU

Intervention groups

1

Description
Intervention group: Metoral + magnesium (1-3 mg⁄kg) per hour Metoral equivalent to 3 cc and 2 g of menium equivalent to 4 cc are injected and (by 2 5 cc syringes)
Category
Treatment - Drugs

2

Description
Control group: (Metoral) 1-3 mg⁄kg per hour Metoral equivalent to 3 cc and 4 cc of distilled water (using 2 5 cc syringes) same shape and same color as the first group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir al-Mominin Hospital
Full name of responsible person
Dorsa Beygi
Street address
Amir al-Momenin (AS) educational and therapeutic center, next to medical school, Basij Square, Arak Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Alireza Kamali
Position
Associate professor
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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