

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

The occurrence of atrial fibrillation or other arrhythmias after surgery

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

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

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malihe safari

Name of organization / entity

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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

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

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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

Latest degree

Specialist

Other areas of specialty/work

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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