

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Investigating the effect of sulfate magnesium tablet on atrial fibrillation after coronary artery bypass grafting in Heshmat Hospital in 2019

Protocol summary

Cardiopulmonary bypass graft surgery, Hospitalization time in ICU and hospital

Study aim

Determination of the prophylactic role of magnesium tablets on reduction of atrial fibrillation rhythm in patients undergone coronary artery bypass graft surgery

Design

A randomized clinical trial, phase 3 with parallel groups, that includes a control group, design of 70 patients.

Settings and conduct

This study will be done at Heshmat Hospital in Rasht on patients undergoing Coronary artery bypass graft surgery. Seventy patients randomly and with quadruple block method will be divided in two groups of magnesium sulfate and control. Magnesium level of plasma will be controlled daily for both groups And if it was higher than normal, the medication will be discontinued for the intervention group. Patients who have arterial fibrillation(AF) rhythm in the monitor for more than 30 seconds are considered as AF+ patients. Finally, the data will be compared in 2 groups. This study does not require blindness and patients and the surgeon are aware of the process.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Only cardiopulmonary bypass graft surgery (not associated with valve operation). First-time open heart surgery. Ejection Fraction(EF) more than 35%. Non-inclusion Criteria: History of Previous arterial fibrillation(AF), History of kidney disease, History of showing an allergic reaction to magnesium, History of taking antiarrhythmic drugs.

Intervention groups

Intervention group: A 250 milligrams magnesium tablet (produced by the 21st-century company) will be prescribed daily from 48 hours before the operation. After the operation and transferred to ICU, if the patient is extubated, orally and if still intubated, through NGT tube, he will receive next doses till the fifth-day after the operation. The control group won't receive any drug.

Main outcome variables

Arterial fibrillation rhythm in patients undergoing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043252N1**

Registration date: **2019-05-18, 1398/02/28**

Registration timing: **prospective**

Last update: **2019-05-18, 1398/02/28**

Update count: **0**

Registration date

2019-05-18, 1398/02/28

Registrant information

Name

gholamreza kanani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sulfate magnesium tablet on atrial fibrillation after coronary artery bypass grafting in Heshmat Hospital in 2019

Public title

The effect of sulfate magnesium on atrial fibrillation after open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Only cardiopulmonary bypass graft surgery (not associated with valve operation). First-time open heart surgery Ejection Fraction(EF) more than 35%

Exclusion criteria:

History of Previous arterial fibrillation(AF) History of kidney disease History of taking magnesium and showing an allergic reaction History of taking antiarrhythmic drugs (such as amiodarone -digoxin -warfarin) Being pregnant Having a pacemaker AV BLOCK In the ECG

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected based on inclusion criteria and then classified into two groups receiving magnesium sulfate and control group, using the random block method in quadruple blocks based on the obtained list. To generate random sequences in this clinical trial, <http://www.graphpad.com/quickcalcs/index.cfm> will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Of Guilan University Of Medical Sciences

Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.GUMS.REC.1397.493

Health conditions studied**1****Description of health condition studied**

Atrial fibrillation and fluttery

ICD-10 code

شماره 148

ICD-10 code description

IX 100-199 Diseases of the circulatory system

Primary outcomes**1****Description**

Effect on prevention of AF rhythm in patients with coronary artery bypass graft surgery

Timepoint

24-hour patient monitoring until the fifth day

Method of measurement

ECG monitoring

Secondary outcomes**1****Description**

Reducing hospitalization time in the ICU and hospital, and thus reducing patient hospitalization costs

Timepoint

After patient's discharge from hospital

Method of measurement

Number of hospitalization days

Intervention groups**1****Description**

Intervention group: All pre-operative patients will be interviewed and the method will be explained to them and written informed consent will be obtained. In both groups, a blood sample for magnesium serum will be

taken first and if it is within the normal range (1/5-2/5 milliequivalents per liter), from 48 hours pre-operation, a 250 milligrams magnesium tablet (manufacturer: 21st century) will be given to intervention group at 6 am. This step is done by a collaborator nurse. After surgery and transfer to the ICU, both groups of patients undergo intensive care and ECG monitoring. The intervention group, in case of staying intubated they will take the tablet through NGT tube and if extubated they will take it orally their next 6 am tablet and it will be continued till the fifth day after surgery. The nurse giving the drug to the patient is not in the care team. Magnesium level of plasma in both groups will be controlled daily and if it was higher than the normal range, the medication will be stopped. All this time, a collaborator anesthetist is aware of receiving the drug by intervention group and will intervene immediately in the event of a complication.

Category

Prevention

2**Description**

Control group: This group does not receive any drug.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Heshmat Hospital

Full name of responsible person

Dr Gholamreza Kanani

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Heshmat Hospital, at the beginning of bayani street, Mosalla Square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

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

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Gholamreza Kanani

Position

Assistant Professor of Cardiology

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Gholamreza Kanani

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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