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

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

InclusionCriteria: 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 Cardiopulmonary bypass graft surgery, Hospitalization time in ICU and hospital

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)

Phone

+98 13 3366 9066

Email address

dr_kanani@gums.ac.ir

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
148 شماره

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

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

City
Rasht

Province
Guilan

Postal code
4144654839

Phone
+98 13 1666 9064

Email
heshmat@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Doctor Shadman Nemati

Street address
Vice Chancellor for research of Guilan,Shahid Siadati Avenue, Namjoo Street

City
Rasht

Province
Guilan

Postal code
4144666949

Phone
+98 13 3333 5821

Fax
+98 13 3333 6395

Email
drshadmannemati_ent@yahoo.com

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

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

City
Rasht

Province
Guilan

Postal code
4144654839

Phone
+98 13 3366 9066

Fax

Email
dr_kanani@gums.ac.ir

Person responsible for scientific

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

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

City
Rasht

Province
Guilan

Postal code
4144654839

Phone
+98 13 3366 9066

Fax

Email
dr_kanani@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Mohadese Ahmadi

Position
Research Expert/(MSc) English

Latest degree
Master

Other areas of specialty/work
Research Expert

Street address
Anestesiology Reseaech Center, Alzahra Hospital, Namjoo Street

City
Rasht

Province
Guilan

Postal code
4144654839

Phone
+98 13 3336 9328

Email
p.ahmadi2311@gmail.com

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