

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Comparison between oral magnesium supplement before surgery and IV administration of magnesium during induction in prevention of hypomagnesemia and arrhythmia after coronary surgery in hospitals related to Shiraz University of Medical sciences

Protocol summary

Summary

This is a RCT study with 2 groups (intervention and control) that the intervention group receives magnesium hydroxide before operation and the control group receives mgso4 after induction of anesthesia. The sample size is at least 36 in each group that it is increased to 43 considering loss to follow up rate of 20%. The goals are: studying the effects of oral magnesium in prevention of arrhythmia and decreasing in hypomagnesaemia rate after CABG, studying intravenous magnesium effects in prevent of arrhythmia and hypomagnesaemia after CABG. The patient who is candidate for CABG enters the study. If one of them has the history of arrhythmia that did not treat, having the history of renal failure or liver dysfunction, patients who have re-operation after main operation, patients who have received b-blocker or ca-blocker before operation because of arrhythmia and patients who are treated with magnesium before operation are excluded from study. The interventions which were done in this study include: taking blood sample for serum magnesium examination and taking electrocardiogram before operation, giving oral magnesium supplement (MOM) to the intervention group before operation and intravenous magnesium (mgso4) to the control group, taking serum magnesium sample during rewarming when the patient is under CPB, checking EKG monitoring for finding existence of arrhythmia before ,during and after CPB , taking serum magnesium sample at the entrance to the intensive unit care (ICU) and repeat it 6,12,24 and 48 hours after this ,taking EKG the entrance time ,24 and 48 hours after it and checking them for presence f arrhythmia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052122359N1**

Registration date: **2015-11-11, 1394/08/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-11, 1394/08/20

Registrant information

Name

Lale Eshaqi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 198 5893

Email address

stud2992736228@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison between oral magnesium supplement before surgery and IV administration of magnesium during induction in prevention of hypomagnesemia and arrhythmia after coronary surgery in hospitals related to Shiraz University of Medical sciences

Public title

Comparison between oral and IV infusion of magnesium on arrhythmia and hypomagnesemia after heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All patients who are candidates for Coronary Artery Bypass Grafts in Shiraz University of Medical Sciences hospitals without Renal Failure, liver failure, no B- blocker or Ca- blocker preoperatively cause of arrhythmia, no preoperative Magnesium therapy .
Exclusion criteria: Re-operation after main surgery because of hemorrhage, IABP usage .

Age

From **40 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Shiraz University of Medical Sciences.

Street address

Zand , St.

City

Shiraz

Postal code

Approval date

2015-05-24, 1394/03/03

Ethics committee reference number

IR.SUMS.REC.1394.9

Health conditions studied

1

Description of health condition studied

Arrhythmia

ICD-10 code

I20,I21,I2

ICD-10 code description

Ischaemic heart diseases

2

Description of health condition studied

hypomagnesemia

ICD-10 code

E87.8

ICD-10 code description

Other disorders of electrolyte and fluid balance, not elsewhere classified

Primary outcomes

1

Description

Serum magnesium level

Timepoint

pre operation, during cardiopulmonary bypass and 6,12,24,48 hours after CABG

Method of measurement

Serum Magnesium has been tested with dirui-cs800 set and with xylidyl blue test.

2

Description

Heart rhythm

Timepoint

48 hours after CABG

Method of measurement

Heart monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Mg-so4 20% was given to the 43 patients in control group after anesthesia induction. Then during CPB, before rewarming take the blood sample and after opening cross clamp . 2gr Mgso4 inserted to the circuit. At the end of operation in ICU took another sample. Other samples have been taken after 6,12,24 and 48 hours after surgery. EKG-monitoring was done during these 2 days.

Category

Treatment - Drugs

2**Description**

20-30cc Mg- Hydroxide15% was given to the intervention group with NGT after anesthesia induction. Then during CPB, before rewarming take the blood sample and after opening cross clamp . 2gr Mgso4 20% inserted to the circuit.At the end of operation in ICU took another sample. Other samples have been taken after 6.12,24 and 48 hours after surgery. EKG-monitoring was done during these 2 days.

Category

Treatment - Drugs

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

Namazi hospital

Full name of responsible person

Janati Mansor

Street address

Namazi hospital ,Namazi square .

City

Shiraz

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

Vice chancellor for research,Shiraz University of Medical Sciences

Full name of responsible person

Postforosh

Street address

Zand, St

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research,Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Janati Mansor

Position

Associate Professor of cardiovascular surgery

Other areas of specialty/work**Street address**

Namazi hospital ,Namazi square .

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Fax**Email**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Associate Professor of cardiovascular surgery

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Eshaqi Lale

Position

Master student of Perfusion

Other areas of specialty/work**Street address**

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Email

l.eshaqi@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty