

# 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 .

**City**

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**Postal code****Phone**

+98 71 3647 4270

**Fax****Email**

janatim@sums.ac.ir

**Web page address****Person responsible for scientific 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**

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Eshaqi Lale

**Position**

Master student of Perfusion

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## **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*