

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Determination of optimal prophylactic dose of magnesium sulfate for prevention of atrial fibrillation after CABG surgery

#### Protocol summary

##### Summary

This is a randomized double blind clinical trial study which will be conducted on 120 patients undergoing elective coronary artery bypass graft (CABG) surgery at Mazandaran Heart center, Sari, Iran. 120 Patients who meet inclusion criteria randomly divided into 3 equal groups. Group 1, 2 and 3 respectively receive 60, 80 and 100 mg/kg magnesium sulfate via cardioplegic solution during aortic cross clamp. Then all patients will be monitored for 3 days after surgery regarding occurrence of postoperative atrial fibrillation (AF). After collecting and classifying of information, data will be analyzed with SPSS18.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201211124365N15**

Registration date: **2012-12-15, 1391/09/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-15, 1391/09/25

##### Registrant information

##### Name

Afshin Gholipour Baradari

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3326 1245

##### Email address

gholipourafshin@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

##### Expected recruitment start date

2011-05-22, 1390/03/01

##### Expected recruitment end date

2012-05-21, 1391/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determination of optimal prophylactic dose of magnesium sulfate for prevention of atrial fibrillation after CABG surgery

##### Public title

Determination of optimal prophylactic dose of magnesium sulfate for prevention of atrial fibrillation after CABG surgery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: signing informed consent; candidate for elective CABG based on angiography; use of cardiopulmonary bypass (CBP) during surgery; no previous history of any cardiac dysrhythmias that is under treatment ( including AF); hemodynamic stability ( MAP>50, heart rate between 50-110); age between 35&75 years old. Exclusion criteria: history of heart failure (Ejection Fraction less than 30%); more than 4 grafts; renal failure ( serum creatinine >1.5 in two consecutive test); hepatic failure ( liver function tests more than 1.5 times of normal value); history of COPD; hyperthyroidism; serum PH < 7.25 or > 7.55;

postoperative MI; second or third degree AV block; need for pacemaker after surgery; reoperation for any reason; history of previous cardiac surgery; anti-arrhythmic drugs consumption (except beta blocker).

#### Age

From **35 years** old to **75 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Mazandaran University of Medical Sciences

##### Street address

Moallem Square, Mazandaran University of Medical Sciences

##### City

Sari

##### Postal code

46175866

#### Approval date

2011-02-05, 1389/11/16

#### Ethics committee reference number

89-130

## Health conditions studied

### 1

#### Description of health condition studied

Atrial fibrillation

#### ICD-10 code

I48

#### ICD-10 code description

Atrial fibrillation and flutter

## Primary outcomes

### 1

#### Description

Atrial fibrillation

#### Timepoint

up to 3 days after operation

#### Method of measurement

ECG monitoring

## Secondary outcomes

### 1

#### Description

PH

#### Timepoint

Before trial, during the operation, 1st day, 2nd day and 3th day after operation, during the operation, 1st day, 2nd day and 3th day after operation

#### Method of measurement

Laboratory kit

### 2

#### Description

K

#### Timepoint

Before trial, during the operation, 1st day, 2nd day and 3th day after operation, during the operation, 1st day, 2nd day and 3th day after operation

#### Method of measurement

Laboratory kit - mEq/L

### 3

#### Description

Mg

#### Timepoint

Before trial, during the operation, 1st day, 2nd day and 3th day after operation, during the operation, 1st day, 2nd day and 3th day after operation

#### Method of measurement

Laboratory kit - mg/dl

## Intervention groups

### 1

#### Description

Intervention 1: 60 mg/Kg MgSO4 via cardioplegic solution during cross clamping

#### Category

Prevention

### 2

#### Description

Intervention 2: 80 mg/Kg MgSO4 via cardioplegic solution during cross clamping

#### Category

Prevention

**3**

**Description**

Intervention 3: 100mg/Kg MgSO4 via cardioplegic solution during cross clamping

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mazandran Heart Center

**Full name of responsible person**

Afshin Gholipour Baradari, MD

**Street address**

Mazandaran Heart center, Artesh Blvd

**City**

Sari

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Mazandaran University of Medical Sciences

**Full name of responsible person**

Ahmad Ali Enayati, MD

**Street address**

Moallem Square, Mazandaran university of medical sciences

**City**

Sari

**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 of Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Afshin Gholipour Baradari, MD

**Position**

CCMF, Associate Professor, Chief of ICU

**Other areas of specialty/work**

**Street address**

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**Name of organization / entity**

Mazandaran University Of Medical Sciences

**Full name of responsible person**

Rahman Ghafari MD

**Position**

Assistant Professor, Cardiac Surgeon

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**Position**

Associate professor

**Other areas of specialty/work**

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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*