Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the efficacy of intravenous administration of magnesium and pottasium solution in cardioversion of postoperative atrial fibrillation: a randomized, double blind, placebo-controlled trial

Protocol summary

Study aim
Evaluation of the efficacy of intravenous administration of magnesium and pottasium solution in cardioversion of postoperative atrial fibrillation

Design
Phase III, Randomized, Double blind, Placebo-Controlled trial, with a parallel group design of 360 patients. Randomization was done with permuted random block

Settings and conduct
The study performs on post operative atrial fibrillation patients who underwent isolated coronary artery bypass graft surgery, in Tehran Heart Center.After random assignment to groups A and B, patients are treated according to the study protocol. If atrial fibrillation persists after 6 hours, both groups would be treated with Amiodarone protocol. The blind group includes the patient, the data collector, the researcher, and the outcome assessor

Participants/Inclusion and exclusion criteria
The inclusion criteria are: atrial fibrillation occurrence after isolated coronary artery bypass graft surgery that ontinued for at least 15 minutes after initiation, serum Potassium level of 4 - 4.5 and serum Magnesium level of 2 - 3.5 meq/L, and having the informed consent to participate in the study The exclusion criteria are: unstable hemodynamic, history of atrial fibrillation before surgery, serum creatinine level more than 1.4 mg/dl, patients receiving packed cell or Inotrope, Hemoglobin level less than 7 g/L, spontaneous cardioversion before randomization

Intervention groups
Intervention group (A): administration of a Metohexal tablet 47.5 mg and Potassium/Magnesium solution. If atrial fibrillation persists after 6 hours, Amiodarone infusion would be initiated control group (B): administration of a Metohexal tablet 47.5 mg and placebo. If atrial fibrillation persists after 6 hours, Amiodarone infusion would be initiated

Main outcome variables
Cardioversion of post operative atrial fibrillation after isolated coronary artery bypass graft surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180430039488N2**
Registration date: **2020-05-03, 1399/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-03, 1399/02/14**
Update count: **0**

Registration date
2020-05-03, 1399/02/14

Registrant information

Name
Farzad Masoudkabir

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8802 9600

Email address
fmasoudkabir@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of intravenous administration of magnesium and pottasium solution in cardioversion of postoperative atrial fibrillation: a randomized, double blind, placebo-controlled trial

Public title

Efficacy of intravenous administration of magnesium and pottasium solution in cardioversion of postoperative atrial fibrillation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Atrial fibrillation after isolated coronary artery bypass graft surgery Continuation of atrial fibrillation rhythm for at least 15 minutes after initiation Serum Potassium level of 4-4.5 meq/L Serum Magnesium level of 4-4.5 meq/L Informed consent to participate in the study

Exclusion criteria:

Unstable hemodynamic (systolic blood pressure less than 90 mmHg) History of atrial fibrillation (persistent or paroxysmal) before surgery Serum creatinine level more than 1.4 mg/dl More than 12 hours have passed since the beginning of the atrial fibrillation rhythm Patients receiving packed cell Hemoglobin level less than 7 g/L Spontaneous cardioversion before randomization Patients receiving Inotrope

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **360**

Randomization (investigator's opinion)

Randomized

Randomization description

permuted block randomization containing 4 subjects in each block eg : AABB. A refers to intervention group and B refers to controls.

Blinding (investigator's opinion)

Double blinded

Blinding description

After randomization and assignment of patients to group A or B, the appropriate solution for each group is prepared and infused by the nurse according to the protocol, but the patient,the person collecting the data, the researcher and the evaluator of the outcome will be unaware of the patient's treatment group as well as the type of solution that the patient has received. Collected data of the study will be entered in the SPSS and then analysed by an independent expert from Tehran heart center research institute.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Jala-Al-ahmad highway, North Kargar street

City

Tehran

Province

Tehran

Postal code

3135674193

Approval date

2019-07-21, 1398/04/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.343

Health conditions studied

1

Description of health condition studied

Postoperative atrial fibrillation

ICD-10 code

I97.89

ICD-10 code description

Other postprocedural complications and disorders of the circulatory system, not elsewhere classified

Primary outcomes

1

Description

Cardioversion of atrial fibrillation to sinus rhythm within the first 6 hour

Timepoint

From the start of the intervention until 6 hours later

Method of measurement

Cardiac rhythm monitoring

Secondary outcomes

1

Description
Time required to convert atrial fibrillation rhythm to sinus rhythm (in the first 6 hours)
Timepoint
From the start of the intervention until 6 hours later
Method of measurement
Cardiac rhythm monitoring

2

Description
Heart rate less than 110 beats per minute during the first 3 hours of treatment
Timepoint
From the start of the intervention until 3 hours later
Method of measurement
Cardiac rhythm monitoring

3

Description
The rate of recurrence of atrial fibrillation in the first 48 hours after the restoration of sinus rhythm
Timepoint
From the time of sinus rhythm restoration to 48 hours later
Method of measurement
Cardiac rhythm monitoring

4

Description
The rate of sinus rhythm restoration within 24 hours of Amiodarone initiation
Timepoint
From the initiation of Amiodarone infusion to 24 hours later
Method of measurement
Cardiac rhythm monitoring

5

Description
The cumulative dose of Amiodarone required to restore sinus rhythm
Timepoint
From the initiation of Amiodarone infusion to restoration of sinus rhythm
Method of measurement
The total amount of Amiodarone that is prescribed until restoration of sinus rhythm

6

Description
The time required to restore the sinus rhythm after initiation of Amiodarone infusion
Timepoint
From the initiation of Amiodarone infusion to restoration of sinus rhythm
Method of measurement
Total sum of time, in minutes, from the initiation of Amiodarone infusion to restoration of sinus rhythm

7

Description
The rate of bradycardia (heart rate less than 60/minute) in the first 6 hours after starting intervention
Timepoint
From the start of the intervention until 6 hours later
Method of measurement
Cardiac rhythm monitoring

8

Description
The rate of systolic blood pressure less than 90 mm Hg in the first 6 hours after starting intervention
Timepoint
From the start of the intervention until 6 hours later
Method of measurement
Blood pressure monitoring

Intervention groups

1

Description
Intervention group: administration of a Metoprolol succin tablet 47.5 mg (Metohexal) and Potassium/Magnesium solution (10 cc of 15% potassium chloride solution of Shahid Ghazi company and 4 cc of 50% magnesium sulfate solution of Shahid Ghazi company diluted in 250 cc of half saline serum, infused over 60 minutes). If the sinus rhythm does not restore after 6 hours, Amiodarone infusion (150 mg Amiodarone of Alborz Daru company within 10 minutes, then 1 mg per minute for 6 hours, and then 0.5 mg per minute for 18 hours) would be initiated. After Amiodarone infusion, the patient is treated with 200 mg Amiodarone tablets every 12 hours. If restoration of sinus rhythm occurs within the first 6 hours, Amiodarone will not be prescribed.
Category
Treatment - Drugs

2

Description
Intervention group: administration of a Metoprolol succin tablet 47.5 mg (Metohexal) and placebo (250 cc of half saline serum, infused over 60 minutes). If the sinus rhythm does not restore after 6 hours, Amiodarone infusion (150 mg Amiodarone of Alborz Daru company within 10 minutes, then 1 mg per minute for 6 hours, and then 0.5 mg per minute for 18 hours) would be initiated. After Amiodarone infusion, the patient is treated with 200 mg Amiodarone tablets every 12 hours. If restoration of sinus rhythm occurs within the first 6 hours, Amiodarone will not be prescribed.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Heart Center
Full name of responsible person
Farzad Masoudkabir
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Farzad Masoudkabir
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Particular parts of the data will be released
When the data will become available and for how long
After release of the results
To whom data/document is available
Scientific institutions
Under which criteria data/document could be used
Further analysis
From where data/document is obtainable
Zohre Mohammadi ,MD
What processes are involved for a request to access data/document
Formal or official request by an institution
Comments