Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effects of oral low dose amiodarone in prevention of atrial fibrillation after coronary artery bypass graft (A Placebo-Controlled Randomized Clinical Trial)

Protocol summary

Summary

The main objectives of the study are the effect of administration of low dose amiodarone on the incidence of atrial fibrillation, ICU (Intensive Care Unit) stay and hospital stay following coronary bypass surgery in the intervention and control groups. It is told to the patients that they may take amiodarone or placebo in the informed consent. Therefore, patients are not aware of their therapeutic group. The patients and medical staff are not aware of the type of tablets in the boxes (amiodarone or placebo). Only the researcher is aware of the code written on the boxes of the tablets; so, this study is a double-blind, parallel clinical trial. Inclusion criteria include patients with coronary artery disease (on angiography). Exclusion criteria are patients above 80 years old, patients with heart valve disease or arrhythmia, history of using anti-arrhythmic drugs or pacemaker. One hundred-seventy patients using random numbers (created by computer) are divided into intervention and control groups. Thus, 85 cases in each treatment arm are randomized to receive placebo or amiodarone. In the intervention group, a total of 4.2 grams oral amiodarone is administered as: 600 mg, the night before surgery and 600 mg, on the morning of surgery and then from the first day after operation followed by 200 mg every eight hours for five days after surgery. Patients in the control group receive placebo (ineffective pill with similar size to amiodarone). In this study the main outcome variable is the atrial fibrillation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207303799N4**
Registration date: **2013-05-04, 1392/02/14**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-05-04, 1392/02/14

Registrant information

Name
Nasim Shayan
Name of organization / entity
Cardiac Transplantation Research Center (CTRC)
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of oral low dose amiodarone in prevention of atrial fibrillation after coronary artery bypass graft (A Placebo-Controlled Randomized Clinical Trial)

Public title

Oral low dose Amiodarone and prevention of atrial fibrillation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with coronary artery disease (on angiography) who are candidate for coronary artery bypass. Exclusion criteria: 1- Patients above 80 years old. 2- Patients who have atrial fibrillation before surgery. 3- Patients with heart valve disease or arrhythmia or having every degree of heart block conduction. 4- Patients who use a pacemaker. 5- Patients who have chronic lung, liver or kidney disease. 6- Patients who have other heart surgeries simultaneously with bypass surgery. 7- Patients who are allergic to amiodarone or in any way giving amiodarone to them is contraindicated. 8- Having sick sinus syndrome.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2012-06-09, 1391/03/20

Ethics committee reference number

90-03-94-15571-53060

Health conditions studied

1

Description of health condition studied

Coronary Artery Diseases

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

AF rhythm

Timepoint

From the second day of the intervention and after CABG surgery, continuous monitoring for the first 72 hours and then daily ECG is done until discharge.

Method of measurement

ECG recording device

2

Description

Length of stay in ICU

Timepoint

At the time of transferring to the ward

Method of measurement

Refer to the data sheet in ICU

3

Description

Duration of hospital stay

Timepoint

At discharge time

Method of measurement

Refer to the Patient file

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group with systolic blood pressure above 80 mmgh and rate of more than 60/min, a total of 4.2 grams oral amiodarone is administered as: 600 mg, the night before surgery and also 600 mg, on the morning of surgery and then from the first day after operation followed by 200 mg every 8 hours for five days after surgery. Amiodarone is an antiarrhythmic drug used for various types of cardiac dysrhythmias, both ventricular and atrial. In this study, the oral form of amiodarone is used. Each tablet contains 200 mg amiodarone hydrochloride. This product is manufactured

by Amin pharmaceutical company.

Category

Prevention

2

Description

Patients in the control group receive placebo pills which are specifically designed to have no real effect. They are made of an inert substance. These tablets in terms of size, shape, packaging and name are exactly similar to the amiodarone tablets. Only the code written on the boxes are different from each other. Frequency and duration of using placebo pills in the control group are absolutely the same as amiodarone pills in the intervention group. This product is manufactured by Amin pharmaceutical company.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Nasim Shayan (Masters in management)

Street address

Dr. Shariati Hospital, North Karegar Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences Vice chancellor for research

Full name of responsible person

Dr. Akbar Fotouhi (Research Deputy of Tehran University of Medical Sciences)

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

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 Vice chancellor for research

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

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Full name of responsible person

Nasim Shayan

Position

Executive director of Cardiac Surgery and Transplantation Research Center/ Masters in management

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Full name of responsible person

Dr. Mahmoodreza Sarzaeem

Position

Assistant Professor of Heart Surgery

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