

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of the Effect of Amiodarone on Prevention of Arrhythmias in Patients underwent Coronary Artery Bypass Graft Surgery

Protocol summary

Summary

Objective: To evaluate the effect of Amiodarone in preventing arrhythmia in patients undergoing coronary artery bypass surgery. Study design: double-blind randomized Clinical Trial. Inclusion criteria: Patients who completed written consent to participate in the study and candidate for CABG; patients older than 18 years. Exclusion criteria: diabetes; hypothyroidism or hyperthyroidism Cr> 2; liver failure (increased SGOT; SGPT) and patients with chronic obstructive pulmonary diseases (except asthma; bronchitis and emphysema); AF; under 18 years of age; pregnancy and EF more than 30% are the exclusion criteria. Intervention: 60 patients were randomly divided into the two groups; however in the study group patients received infusion of Amiodarone (3mg / kg) 10 minutes before declamping of the aorta and in the control group patients received 10cc of saline 10 minutes before declamping of the aorta. Three minutes before aortic clamp removal; syringes containing (Amiodarone or placebo) are injected through 30 minutes; cardiac arrhythmia such as premature ventricular contractions; premature atrial contractions; PVC bigeminy and trigeminy; branch blocks; asystol; VT and VF; etc. will be recorded. All interventions carried out with cardio-surgeon or anesthesiologist and cardiac arrhythmia will be recorded after chest tube insertion and close the sternum up to 24 hours after patient arrival to the ICU.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016053014372N7**

Registration date: **2016-06-29, 1395/04/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-29, 1395/04/09

Registrant information

Name

Simin Azemati

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4270

Email address

azemati@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Science

Expected recruitment start date

2016-04-18, 1395/01/30

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Amiodarone on Prevention of Arrhythmias in Patients underwent Coronary Artery Bypass Graft Surgery

Public title

Evaluation of the Effect of Amiodarone on Prevention of Arrhythmias in Patients underwent Coronary Artery Bypass Graft Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients who completed written consent to participate in the study and candidate for CABG; patients older than 18 years. Exclusion criteria: diabetes; hypothyroidism or hyperthyroidism Cr> 2; liver failure (increased SGOT; SGPT) and patients with chronic obstructive pulmonary diseases (except asthma; bronchitis and emphysema); AF; under 18 years of age; pregnancy and EF more than 30% are the exclusion criteria.

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiaz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2016-02-17, 1394/11/28

Ethics committee reference number

IR.SUMS.Med.RED.1394.205

Health conditions studied

1

Description of health condition studied

coronary arthery heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

REPERFUSION VENTRICULAR FIBRILATION

Timepoint

30 min after declamping

Method of measurement

MONITOR OF EKG

2

Description

Arrhythmia

Timepoint

during 24 h of ICU stay

Method of measurement

MONITOR OF EKG AND EKG

Secondary outcomes

empty

Intervention groups

1

Description

in the intervention group patients received infusion of Amiodarone(HAMELN-GERMANY) (3mg / kg) 10 minutes before decamping of the aorta a

Category

Treatment - Drugs

2

Description

in the control group patients received 10cc of saline 10 minutes before decamping of the aorta

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Sima Eghdami

Street address

Namazi squer, Namazi Hospital

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Seed Basir Hashemi

Street address
Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand streetl

City
Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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
Sima Eghdami

Position
Perfusionist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr SIMIN AZEMATI

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Cardio, Anesthesiologist

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Person responsible for updating data

Contact

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Shiraz anesthesiology and critical care research center

Full name of responsible person
Farzaneh Masihi

Position
English Consultant

Other areas of specialty/work

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Shiraz Anesthesiology and Critical Care Research Center, Research Tower, 5 th floor, Khalili street

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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

