Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
125.1
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

Street address

Anesthesiology Department- Faghihi Hospital- Zand Street

City

Shiraz

Postal code

Phone

+98 71 3647 4270

Fax

Email

sims_eghdami@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Dr SIMIN AZEMATI

Position

Cardio,Anesthesilogist

Other areas of specialty/work

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Postal code

Phone

+98 71 3647 4270

Fax

Email

azematis@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz anesthesiology and critical care research center

Full name of responsible person

Farzaneh Masihi

Position

English Consultant

Other areas of specialty/work

Street address

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

City

Shiraz

Postal code

Phone

+98 71 3647 4270

Fax

Email

masihifarzaneh@yahoo.com

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

Data Dictionary	*empty*