

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Amiodarone versus propafenone to treat atrial fibrillation after coronary artery bypass graft surgery

Protocol summary

Summary

This study has been planned to compare the effectiveness of these two drugs in hospitalized patients after CABG ,to find out the optimal treatment for atrial fibrillation.All candidates for heart surgery (on pump CABG); who fill out the consent form to participate in research, will be included. And all patients with a history of sensitivity to propafenone; 'EF <30%; cardiogenic shock; bradycardia; marked hypotension; sick sinus; electrolyte imbalance will be excluded.Patients will be devided into tow groups.In the first group propafenone and in the second group amiodarone will be administered.Drug administration will be done at the early detection of postoperative atrial fibrillation by the ICU nurse and will be confirmed by the ICU spcialist.Also the type of atrial fibrillation and its association with other symptoms such as hypotension will be approved.The investigator will not involve in the intervention and the patients are not aware of the treatment they are receiving .So the study is double blind.At the onset of AF, patients in first group will receive propafenone (600mg PO stat and 150mg Q8h x10 days).And patients in second group will receive amiodarone (300mg stat and 600mg iv infusion in 12-24 hours)..In case of reasonable results in administration of any of these drugs,it can be hoped that by Using proper and appropriate dose ,atrial fibrillation occurrence in patients candidate for open heart surgery ,especially coronary artery bypass surgery will be controlled quickly and more accurately.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809092795N1**

Registration date: **2011-04-16, 1390/01/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-16, 1390/01/27

Registrant information

Name

Mohammad Hassan Nemati

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1235 1085

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Shiraz University of Medical Sciences

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2010-07-23, 1389/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Amiodarone versus propafenone to treat atrial fibrillation after coronary artery bypass graft surgery

Public title

Amiodarone versus propafenone to treat atrial fibrillation after coronary artery bypass graft surgery

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: All candidates for heart surgery (on pump CABG); who fill out the consent form to participate in research. Exclusion criteria: All patients with a history of sensitivity to propafenone; 'EF <30%; cardiogenic shock; bradycardia; marked hypotension; sick sinus; electrolyte imbalance.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size:

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
Ethical committee of Shiraz University of Medical Sciences

Street address
Zand st., Faculty of Medicine

City
Shiraz

Postal code

Approval date
2011-01-02, 1389/10/12

Ethics committee reference number
CT-89-5352

Health conditions studied

1

Description of health condition studied
Atrial fibrillation in hospitalized patients after CABG

ICD-10 code
I97.8

ICD-10 code description

Other postprocedural disorders of circulatory system, not elsewhere classified

Primary outcomes

1

Description
Treatment of atrial fibrillation after heart surgery

Timepoint
Early detection of postoperative AF will be done by the ICU nurse and will be confirmed by ICU specialist.

Method of measurement
Monitoring and ECG use.

Secondary outcomes

empty

Intervention groups

1

Description
.At the onset of AF, patients in first group will receive propafenone (600mg PO stat and 150mg Q8h x10 days).

Category
Treatment - Drugs

2

Description
At the onset of AF, patients in second group will receive amiodarone (300mg stat and 600mg iv infusion in 12-24 hours).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ordibehesht Hospital

Full name of responsible person
Doctor Mohammad Hassan Nemati

Street address
Ordibehesht Hospital, Chamran street ,Shiraz

City
Shiraz

2

Recruitment center

Name of recruitment center
Shiraz Central Hospital

Full name of responsible person
Doctor Mohammad Hassan Nemati

Street address
Shiraz Central Hospital , Chamran street ,Shiraz

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nemati_mhs@sums.ac.ir ; Nemati_mhs@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person
Dr Gholamreza Hatam

Street address
Zand street , Shiraz

City
Shiraz

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, 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
Doctor Mohammad Hassan Nemati

Position
Assistant Professor, Department of Cardiac Surgery

Other areas of specialty/work

Street address
Shiraz University of Medical Sciences ,Zand street

City
Shiraz

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Mohammad Hassan Nemati

Position
Assistant Professor, Department of Cardiac Surgery

Other areas of specialty/work

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Person responsible for updating data

Contact

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