Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of prophylactic effect versus therapeutic effect of amiodarone in patients undergoing heart surgery at risk of atrial fibrillation: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the prophylactic effect versus therapeutic effect of amiodarone in patients undergoing heart surgery at risk of atrial fibrillation

Design

This is a double-blind randomized clinical trial, phase II, in which 200 eligible patients will be randomly assigned to the intervention and control groups.

Settings and conduct

The eligible patients undergoing heart surgery referring to the Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18 to 65 years old; candidate for elective cardiac surgery; having a preoperative sinus rhythm. Exclusion criteria: use of antihypertensive drugs other than beta-blockers or ACE inhibitors; thyroid, renal, pulmonary, hepatic disorders; asthma; bradycardia; heart failure; atrioventricular block; sensitivity to amiodarone.

Intervention groups

Intervention group: intravenous infusion of amiodarone (manufactured by Shahr Daroo Pharmaceutical Co.) 350 mg 24 hours before surgery. Control group: intravenous infusion of amiodarone (manufactured by Shahr Daroo Pharmaceutical Co.) 350 mg 24 hours after surgery.

Main outcome variables

Primary outcome: incidence of atrial fibrillation. Secondary outcome: incidence of side effects (such as hypotension and bradycardia).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N392**
Registration date: **2021-05-02, 1400/02/12**
Registration timing: **prospective**

Last update: **2021-05-02, 1400/02/12**
Update count: **0**

Registration date

2021-05-02, 1400/02/12

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of prophylactic effect versus therapeutic effect of amiodarone in patients undergoing heart surgery at risk of atrial fibrillation: a double-blind randomized clinical trial

Public title
Comparison of prophylactic effect versus therapeutic effect of amiodarone in patients undergoing heart surgery at risk of atrial fibrillation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age: 18 to 65 years old Candidate for elective cardiac surgery Having a preoperative sinus rhythm

Exclusion criteria:
Use of antihypertensive drugs other than beta-blockers or ACE inhibitors Thyroid, renal, pulmonary, hepatic disorders Asthma Bradycardia Heart failure Atrioventricular block Sensitivity to amiodarone

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2021-04-10, 1400/01/21

Ethics committee reference number
IR.UMSHA.REC.1400.071

Health conditions studied

1

Description of health condition studied
Atrial fibrillation

ICD-10 code
I48.91

ICD-10 code description
Unspecified atrial fibrillation

Primary outcomes

1

Description
Incidence of atrial fibrillation

Timepoint
24 hours after surgery

Method of measurement
Using a monitor machine

Secondary outcomes

1

Description
Incidence of side effects (such as hypotension and bradycardia)

Timepoint
24 hours after surgery

Method of measurement
using a monitor machine

Intervention groups

1

Description
Intervention group: Intravenous infusion of amiodarone (manufactured by Shahr Daroo Pharmaceutical Co.) 350 mg 24 hours before surgery
Category
Treatment - Drugs

2

Description
Control group: Intravenous infusion of amiodarone (manufactured by Shahr Daroo Pharmaceutical Co.) 350 mg 24 hours after surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Heart Hospital in Hamadan city
Full name of responsible person
Dr Mehran Jabari Mehrabani
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Sponsors / Funding sources

1

Sponsor
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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
Hamedan 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available