

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

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

School of Medicine,

Phone

+98 81 3838 0572

Email

mehran_jabbari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mehran Jabari Mehrabani

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

mehran_jabbari@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Ahmad Reza Salim Bahrami

Position

Anesthesiologist

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

salimbahramidr@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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