

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of prophylactic and therapeutic effect of amiodarone in heart surgery patients at risk of atrial fibrillation

Protocol summary

Study aim

Comparison of prophylactic and therapeutic effect of amiodarone in heart surgery patients prone to atrial fibrillation

Design

Clinical trial with control group, parallel groups, randomized, 200 patients, randomization by card

Settings and conduct

This study will be performed as a clinical trial on cardiac patients who are candidates for elective surgery. The research will be conducted in Farshchian Educational and Medical Center of Hamedan in 1400. In the intervention group, patients received an intravenous infusion of 350 mg amiodarone 24 hours before surgery. In the postoperative control group, amiodarone is injected three minutes before the removal of the aortic clamp, and within 30 minutes to 24 hours after admission to the ICU, patients are cared for and possible cardiac arrhythmias are recorded.

Participants/Inclusion and exclusion criteria

inclusion criteria: En Candidate patients for elective cardiac surgery ASA class 2 & 3 Consent to participate in the study Having a sinus rhythm before surgery No history of amiodarone allergy exclusion criteria: En Recipients of antihypertensive drugs except beta blockers and ACE inhibitors Patients with thyroid, renal, pulmonary, hepatic disorders Asthmatics Rate of less than 50 Heart failure Atrioventricular block

Intervention groups

In the intervention group, patients will receive an intravenous infusion of 350 mg amiodarone 24 hours before surgery. In the postoperative amiodarone control group, it is injected three minutes before the aortic clamp is removed, and within 30 minutes to 24 hours after admission to the ICU, patients are cared for and in case of cardiac arrhythmias is recorded. if arrhythmia is observed, the patient will be continuously monitored with EKG.

Main outcome variables

Atrial fibrillation: supraventricular tachyarrhythmia with uncoordinated atrial activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210424051058N1**

Registration date: **2021-05-27, 1400/03/06**

Registration timing: **prospective**

Last update: **2021-05-27, 1400/03/06**

Update count: **0**

Registration date

2021-05-27, 1400/03/06

Registrant information

Name

mehran jabari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3111 1300

Email address

mehran_jabbari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prophylactic and therapeutic effect of amiodarone in heart surgery patients at risk of atrial fibrillation

Public title

The effect of Amiodarone in heart surgery patients prone to atrial fibrillation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate patients for elective cardiac surgery ASA class 2 & 3 Consent to participate in the study Having a sinus rhythm before surgery No history of amiodarone allergy

Exclusion criteria:

Recipients of antihypertensive drugs except beta blockers and ACE inhibitors Patients with thyroid, renal, pulmonary, hepatic disorders Asthmatics Rate of less than 50 Heart failure Atrioventricular block

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be randomly assigned to the prevention and Intervention group. For this purpose, 50 cards are prepared and written on 25 letters C means prevention and on the other 25 letters I means the Intervention group and each of them is placed in an envelope with aluminum foil and their lids are glued inside. We put a box. When patients arrive, we randomly remove one of the envelopes and open the lid. According to the selected letter (C or I) inside it, we assign the patient to the prevention and Intervention group. With the selection of each patient, the card is set aside so that all the cards are selected. Then return all the cards to the box and repeat this process four times to reach the desired sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Ethics Committee in Research, Office of Vice Chancellor for Education, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd, Hamadan

City

Hamadan

Province

Hamadan

Postal code

65176-19657

Approval date

2021-04-09, 1400/01/20

Ethics committee reference number

IR.UMSHA.REC.1400.071

Health conditions studied**1****Description of health condition studied**

atrial fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes**1****Description**

Atrial fibrillation: It means uncoordinated atrial activity and consequent mechanical atrial insufficiency.

Timepoint

The outcome of the intervention will be reviewed and compared before the intervention and one week after the intervention.

Method of measurement

ECG

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group, patients will receive 350 mg of amiodarone as an intravenous infusion 24 hours before surgery. Within 30 minutes to 24 hours after admission to the ICU, patients are cared for and in the event of cardiac arrhythmias such as

premature ventricular fibrillation; Premature atrial fibrillation; Branch blocks; Asystole; VT; VF is recorded and also cardiac arrhythmias and interventions performed according to the opinion of the surgeon or anesthesiologist

Category

Treatment - Drugs

2**Description**

Control group: In the control group, amiodarone is injected after surgery and three minutes before removal of the aortic clamp. EKG is taken in case of arrhythmic symptoms (such as palpitations, tachycardia, hypotension, shortness of breath, etc.) and if arrhythmia is observed, the patient will be monitored continuously with EKG.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farshchian hospital

Full name of responsible person

Mehran Jabari

Street address

Farshchian hospital, fahmideh street, Hamadan

City

Hamadan

Province

Hamadan

Postal code

65176-19657

Phone

+98 81 3265 0020

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.saeed bashirian

Street address

Office of Vice Chancellor for Education, International Affairs Directory Hamedan University of Medical Sciences (UMSHA), Building No. 4, fahmideh blv., Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

65176-19657

Phone

+98 81 3253 3254

Email

s_bashirian@yahoo.com

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

Mehran Jabbari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Besat hospital, Shahid Motahary Blv, Hamadan

City

Hamadan

Province

Hamadan

Postal code

65176-19657

Phone

+98 918 811 2759

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

Mehran Jabbari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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Postal code

65176-19657

Phone

+98 918 811 2759

Email

mehran_jabbari@yahoo.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Mehran Jabbari

Position

Resident

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+98 918 811 2759

Email

mehran_jabbari@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Information about the variables studied in this research will be shared.

When the data will become available and for how long

After publishing the relevant article

To whom data/document is available

researchers

Under which criteria data/document could be used

The information that the researchers are looking for should not be exactly the same as the findings of the published article in this study. Apart from the mentioned cases, other analyzes and extraction of information considered by the researchers from the data are unimpeded. The study data will also be provided to researchers without the identity information of the study participants

From where data/document is obtainable

mehran_jabbari@yahoo.com

What processes are involved for a request to access data/document

The researcher must first email the following account and submit his request: mehran_jabbari@yahoo.com If the researcher's request is approved, the data will be emailed to him / her within a maximum of one month.

Comments