Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 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

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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

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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

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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
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Person responsible for updating data

Contact
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Full name of responsible person
Mehran Jabbari
Position
Resident
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Medical doctor
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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