

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Oral Amiodarone Administration on Prevention of Cardiac Arrhythmia Following Open Heart Surgery, a Randomized Clinical trial Study

Protocol summary

Study aim

This study was a randomized, double blind clinical trial. 400 patients with open heart surgery candidates were randomly divided into two groups, with and without (control) amiodarone. Finally, the prevalence of cardiac arrhythmias after surgery until the patient's stay in the intensive care unit is recorded in the questionnaires.

Design

A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 501 patients, enrolled between April 2016 and March 2018, and followed for one year

Settings and conduct

In the intervention group, 200 mg of amiodarone was given orally twice a day until the patient was cleared. Patients in the control group received placebo (vitamin B1). The frequency and duration of use of placebo in the control group were completely similar to the oral administration of amiodarone in the intervention group. Electrocardiogram monitoring was conducted continuously and monitored.

Participants/Inclusion and exclusion criteria

Age over 18 years, [open heart surgery, Sinus rhythm and normal function of liver, renal system, pulmonary system and thyroid. History of atrial and ventricular arrhythmia and cardiac blocks, patient's need for Pace, anti-arrhythmic therapy, Age over 80 years, pregnant patients

Intervention groups

In the intervention group, 200 mg of amiodarone was given orally twice a day until the patient was cleared. Patients in the control group received placebo (vitamin B1). The frequency and duration of use of placebo in the control group were completely similar to the oral administration of amiodarone in the intervention group.

Main outcome variables

Incidence of types of arrhythmia, duration of admission

to ICU, hospitalization time and side effects of amiodarone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151109024975N8**

Registration date: **2018-07-07, 1397/04/16**

Registration timing: **retrospective**

Last update: **2018-07-07, 1397/04/16**

Update count: **0**

Registration date

2018-07-07, 1397/04/16

Registrant information

Name

Gohar Eslami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3695

Email address

g.eslami@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2016-04-20, 1395/02/01
Actual recruitment end date
2018-03-20, 1396/12/29
Trial completion date
empty

Scientific title
Efficacy of Oral Amiodarone Administration on Prevention of Cardiac Arrhythmia Following Open Heart Surgery, a Randomized Clinical trial Study

Public title
Efficacy of Oral Amiodarone in atrial fibrillation after open heart surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Candidate for open heart surgery Preoperative sinus rhythm Normal function of liver, renal system , pulmonary system and thyroid
Exclusion criteria:
History of atrial and ventricular arrhythmia and cardiac blocks with any degree before surgery Patient's need for Pace Anti-arrhythmic therapy before surgery The history of thyroid and lung and renal disease and hepatitis Age over 80 years Pregnant patients Allergy to Amiodarone

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **400**
Actual sample size reached: **400**

Randomization (investigator's opinion)
Randomized

Randomization description
Random method and description of each method: simple randomization After determining the size of the sample, 400 people, 200 in the control group and 200 in the intervention group were considered. By co-ordinating medical records, this number was considered average for the duration of the appointment, and then the list of individuals was determined. The list was prepared based on the patients' turn-by-turn and then, using the random numbers table, the numbers of the control and intervention group were determined and compared to the coordination for the next steps.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and therapists are not aware of the type of drug present in the pills (amiodarone or vitamin B1), and only the researcher knows about the code inserted (code A or code B) on the pill pack.

Placebo

Used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Research Deputy of Mazandaran University of Medical Sciences Moalem Square
City
Sari
Province
Mazandaran
Postal code
48175-861

Approval date
2017-04-09, 1396/01/20

Ethics committee reference number
IR.MAZUMS.REC.95.2146

Health conditions studied

1

Description of health condition studied
Arrhythmia after open heart surgery

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Prevention of various types of arrhythmias after open heart surgery

Timepoint
Duration of hospitalization

Method of measurement
monitoring

Secondary outcomes

1

Description
Duration of admission to ICU

Timepoint
Duration of hospitalization

Method of measurement

Monitoring and file

2

Description

Duration of hospitalization

Timepoint

Duration of hospitalization

Method of measurement

Monitoring and file

3

Description

Side effects of amiodarone

Timepoint

Duration of hospitalization

Method of measurement

Monitoring and file

Intervention groups

1

Description

Control group: Patients in the control group received placebo (vitamin B1). The frequency and duration of placebo in the control group were similar to the oral administration of amiodarone tablets in the intervention group (twice a day and up to discharge). Patients undergoing coronary artery bypass grafting, the drug is fed through the nasopharyngeal tube. The placebo is structurally similar to the amiodarone tablet, which is used in this study with a 300mg of vitamin B1 tablet that looks similar to the 200mg tablet in terms of its appearance.

Category

Placebo

2

Description

Intervention group: 200 mg of amiodarone is given orally twice a day until the patient's discharge. . Patients who underwent coronary artery bypass grafting were injected through the nasopharyngeal tube. . Electrocardiogram monitoring was conducted continuously and monitored and educated nurses monitored the monitor frequently, and if any irregularities in rhythm were observed, they identified the type of arrhythmia of the patients and recorded the questionnaires. Eventually, the prevalence of cardiac arrhythmias and other items in the questionnaire was recorded in the questionnaires up to one week after the open heart surgery in the patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh-zahra hospital Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Street address

Artesh Blvd - Center of the heart of Mazandaran

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3331 4086

Fax

+98 11 3332 4002

Email

g.eslami@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Moalem Square, Research Deputy of Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3325 7230

Fax

+98 11 3326 1244

Email

g.eslami@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Mazandaran University of Medical Sciences, Imam Square, Three Way Joybar, Beginning of Valiasr Highway

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3354 3695

Fax

+98 11 3354 3695

Email

g.eslami@mazums.ac.ir

Web page address

+98 11 3335 2725

Email

g.eslami@mazums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Mazandaran University of Medical Sciences, Imam Square, Three Way Joybar, Beginning of Valiasr Highway

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3354 3695

Fax

+98 11 3335 2725

Email

g.eslami@mazums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Mazandaran University of Medical Sciences, Imam Square, Three Way Joybar, Beginning of Valiasr Highway

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3354 3695

Fax

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