

# 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