

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of ascorbic acid and omega-3 on the incidence of atrial fibrillation and hospitalization after coronary artery bypass graft surgery

Protocol summary

Study aim

Comparison of the effectiveness of ascorbic acid and omega-3 on the incidence of atrial fibrillation and hospitalization after coronary artery bypass graft surgery

Design

The clinical trial has a control group, two intervention groups with parallel, randomized groups.

Settings and conduct

In this prospective study, patients referred to Shahid Rajaei hospital who are candidates for coronary artery bypass graft surgery and have inclusion criteria and no exclusion criteria, will be randomly divided into three groups of control, intervention 1 and intervention 2. Intervention 1 group: In addition to Bisoprolol, Two 1000 mg Omega3 capsules prescribed at least 24 h before operation and daily afterwards Intervention 2 group: In addition to Bisoprolol, consume 2 g effervescent vit. C before operation and 1 g vit C daily till discharging Control group: Just β Blocker (Bisoprolol) is prescribed

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient must have undergone coronary artery bypass surgery, Sinus rhythm on the ECG, pre-operative prescription oral beta-blocker, informed consent. Exclusion criteria: The History of Atrial Fibrillation, Severe renal, Pulmonary and liver diseases, Heart Blocks, Severe Heart Valve disease, Taking Digoxin and Antiarrhythmic drugs, Sensitivity to Ascorbic acid or Omega-3, Ejection Fraction less than 40%, Using of vitamin supplements containing antioxidants or omega-3 supplements in the last 3 days before surgery

Intervention groups

Intervention group 1: In addition to Bisoprolol, two 1000 mg Omega3 capsules prescribed at least 24 hours before operation and daily afterwards till discharging Intervention group 2: In addition to Bisoprolol, consume 2 g vit. C before operation and 1 g vit C daily till discharging Control group: Just β Blocker (Bisoprolol) is

prescribed

Main outcome variables

Atrial fibrillation rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171114037462N1**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **retrospective**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

Registration date

2020-04-14, 1399/01/26

Registrant information

Name

Fatemeh Bayat

Name of organization / entity

Alborz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2285 1284

Email address

bayatlaleh@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-17, 1397/06/26

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date

2018-09-17, 1397/06/26
Actual recruitment end date
 2019-11-06, 1398/08/15
Trial completion date
 2020-03-10, 1398/12/20

Scientific title
 Comparison of the effectiveness of ascorbic acid and omega-3 on the incidence of atrial fibrillation and hospitalization after coronary artery bypass graft surgery

Public title
 Comparison of the effectiveness of ascorbic acid and omega-3 on the incidence of atrial fibrillation and hospitalization

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 The Patient must have undergone Coronary artery bypass graft surgery Before surgery, the patient's ECG's rhythm should be sinusoidal Preoperative oral beta-blocker administration to the patient Informed consent
Exclusion criteria:
 Using of vitamin supplements containing antioxidants or omega-3 supplements in the last 3 days History of atrial fibrillation History of congenital heart disease History of severe valvular disease Sensitization to omega-3 or vitamin C, which is a severe GI complications Permanent or temporary pacemaker Ejection fraction less than 40% Severe respiratory disease ,COPD , pneumonia Severe hepatic disease ,cirrhosis , fulminant hepatitis atrioventricular block or bradycardia less than 50 beats per minute End stages renal disease Taking class 1 and 3 antiarrhythmic drugs or digoxin

Age
 No age limit

Gender
 Both

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **50**
 Actual sample size reached: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Using randomized blocking, patients are randomly divided into 3groups For blocking 6 blocks with four letters are prepared with A and B letters and the selection of blocks is based on random numbers. Group A receives omega 3, group B receives ascorbic acid and the rest are in the control group Intervention group1 :In addition to 2.5 mg Bisoprolol, two 1000 mg omega3 capsules prescribed at least 24 hours before operation and daily afterwards till discharging Intervention group2 : In addition to 2.5 mg Bisoprolol ,consume 2g vit.C before operation and 1g vit C daily till discharging Control group:just β Blocker(Bisoprolol) is prescribed

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 AlborzUniversity of Medical Sciences

Street address

Safarian Alley ,Golshahr,Deputy of Research and Technology

City

Karaj

Province

Alborz

Postal code

3198537646

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.ABZUMS.REC.1397.200

Health conditions studied

1

Description of health condition studied

Atrial Fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

2

Description of health condition studied

Coronary Artery Bypass Graft Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Atrial fibrillation

Timepoint

During Hospitalization using ICU monitoring

Method of measurement

ECG

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Intervention group1 : In addition to 2.5 mg Bisoprolol (Merck Company), two 1000 mg Omega3 capsules prescribed at least 24 hours before operation and daily afterwards till discharging (Pourateb Group)

Category

Prevention

2

Description

Intervention group2: In addition to 2.5 mg Bisoprolol (Merck Company), consume 2 g effervescent v it. C before operation and 1 g vit C daily till discharging

Category

Prevention

3

Description

Control group: Just β Blocker (2.5 mg Bisoprolol, Merck Company) is prescribed

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei hospital

Full name of responsible person

Fatemeh Bayat

Street address

Rajaei Ave, Hesarak, Shahid Beheshti Blvd, Rajaei Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohamad Noorisepehr

Street address

Safarian Alley, Golshahr, Deputy of research and technology

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Fatemeh Bayat

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Main outcome data

When the data will become available and for how long

6 months after publication

To whom data/document is available

everybody

Under which criteria data/document could be used

Systematic review

From where data/document is obtainable

E-mail or phone number

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

check archive and send

Comments