Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 Rajaee 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.Intervention1 group :In addition to Bisoprolol, Two 1000 mg Omega3 capsules prescribed at least 24 h before operation and daily afterwards Intervention2 group:In addition to Bisoprolol, consume 2 g effervescent vit.C before operation and 1 g vit C daily till discharging Control group:Just βBlocker(Bisoprolol) is prescripted

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 group1 :In addition to Bisoprolol, two 1000 mg Omega3 capsules prescribed at least 24 hours before operation and daily afterwards till discharging Intervention group2 : In addition to Bisoprolol ,consume 2 g vit.C before operation and 1 g vit C daily till discharging Control group:Just βBlocker(Bisoprolol) is prescripted

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 Scinece
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 prescripted

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 fibrilation

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 βBlocker(2.5 mg Bisoprolol , Merck Company) is prescripted
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
City
Karaj
Province
Alborz
Postal code
3197635141
Phone
+98 26 3455 2001
Fax
Email
rajaei@abzums.ac.ir
Web page address
https://rajaei.abzums.ac.ir

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
City
Karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3255 8920
Email
rajaei@abzums.ac.ir
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
Street address
Rajaei Ave ,Hesarak,Shahid Beheshti Blvd,Rajaei Hospital
City
Karaj
Province
Alborz
Postal code

3197635141

Phone
+98 26 3457 0030

Email
rajaei@abzums.ac.ir

Person responsible for scientific 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

Street address
Rajaei Ave ,Hesarak,Shahid Beheshti Blvd,Rajaei Hospital

City
Karaj

Province
Alborz

Postal code
3197635141

Phone
+98 26 3457 0030

Email
rajaei@abzums.ac.ir

Person responsible for updating data

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

Street address
Rajaei Ave ,Hesarak,Shahid Beheshti Blvd,Rajaei Hospital

City
Karaj

Province
Alborz

Postal code
3197635141

Phone
+98 26 3457 0030

Email
rajaei@abzums.ac.ir

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