

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Vitamin C in Prevention of Atrial Fibrillation after coronary artery bypass graft (A Placebo-Controlled Randomized Clinical Trial)

Protocol summary

Summary

Main Objectives of the study are the effect of administration of Vitamin C on the incidence of Atrial Fibrillation, ICU stay and hospital stay following coronary bypass surgery in the intervention and control groups. It is told to the patients that they may take vitamin C or placebo (normal saline) in the informed consent. Therefore, patients are not aware of their therapeutic group. The patients and medical personnel are not aware of the type of drug in the serums (vitamin C or normal saline). Only the researcher is aware of the code written on the serum; so, this is a double-blind, parallel clinical trial. Inclusion criteria include patients with coronary artery disease (on angiography). Exclusion criteria are patients above 80 years old, patients with heart valve disease or arrhythmia, history of using anti-arrhythmic drugs or pacemaker. One hundred-seventy patients using random numbers (created by computer) are divided into intervention and control groups. Thus, 85 cases in each treatment arm are randomized to receive placebo or vitamin C. In the intervention group, a total of 7.0 grams intravenous vitamin C is administered as: 2.0 g, 12 hours before surgery and 500 mg twice a day for five days after surgery. Patients in the control group receive placebo (normal saline intravenously). In this study, the main outcome variable is the Atrial Fibrillation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207243799N3**

Registration date: **2012-11-05, 1391/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-05, 1391/08/15

Registrant information

Name

Nasim Shayan

Name of organization / entity

Cardiac Transplantation Research Center (CTRC)

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 3037

Email address

ctrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Vitamin C in Prevention of Atrial Fibrillation after coronary artery bypass graft (A Placebo-Controlled Randomized Clinical Trial)

Public title

Effects of Vitamin C in Prevention of Atrial Fibrillation after coronary artery bypass graft (CABG)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with coronary artery disease (on angiography) who are candidate for coronary artery bypass. Exclusion Criteria: 1- Patients above 80 years old. 2- Patients who have Atrial Fibrillation before surgery. 3- Patients with heart valve disease or arrhythmia or having every degree of heart block conduction. 4- Patients who use a pacemaker. 5- Patients who have chronic lung, liver or kidney disease. 6- Patients who have other heart surgeries simultaneously with bypass surgery. 7- History of using anti-arrhythmic drugs. 8- Having sick sinus syndrome. 9- Having symptoms of urinary stone or history of kidney stones. 10- History of using Vitamin C in the recent quarter.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2012-05-14, 1391/02/25

Ethics committee reference number

90-03-94-15572-53062

Health conditions studied**1****Description of health condition studied**

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes**1****Description**

Duration of hospital stay

Timepoint

At discharge time

Method of measurement

Refer to the Patient file

2**Description**

AF rhythm

Timepoint

Continuous monitoring for the first 72 hours after CABG surgery and then daily ECG

Method of measurement

ECG recording device

3**Description**

Length of stay in ICU

Timepoint

At the time of transferring to the ward

Method of measurement

Refer to the data sheet in ICU

Secondary outcomes

empty

Intervention groups**1****Description**

Patients in the control group receive placebo (Normal Saline intravenously).

Category

Prevention

2**Description**

In the intervention group, a total of 7.0 grams intravenous Vitamin C is administered as: 2.0 g (4 ampules), 12 hours before surgery and 500 mg (1 ampule), twice a day for five days after surgery. In this study, the injection form of Vitamin C or Ascorbic acid is used. This ampule produced by Daroupakhsh company. Each ampule contains 500 mg of Vitamin C in 5 ml that is

used as an IV infusion (in 100 cc of normal saline solution).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Nasim Shayan (Masters in Management)

Street address

Dr. Shariati Hospital, North Karegar Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences Vice chancellor for research

Full name of responsible person

Dr. Akbar Fotouhi (Research Deputy of Tehran University of Medical Sciences)

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Full name of responsible person

Nasim Shayan

Position

Executive Director of Cardiac Surgery and Transplantation Research Center/ Masters in Management

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Cardiac Surgery and Transplantation Research Center of Dr. Shariati Hospital

Full name of responsible person

Dr. Mahmoodreza Sarzaeem

Position

Assistant Professor of Heart Surgery

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty