

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Effect of vitamin c and placebo on pericardial effusion in post cardiac surgery patients with or without anticoagulation therapy

Protocol summary

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Summary

The aim of this study is access of effect of vitamin c and placebo on pericardial effusion in post cardiac surgery patients with or without anticoagulation therapy. In this clinical randomized trial 400 patients (18 years old and older) who had different cardiac surgery (coronary artery bypass, valvular heart surgery, and simple cardiac surgery), divided into two groups, study group who receive vitamin c and control group who receive placebo. Echocardiographic evaluation will be performed for all the patients at the first and 3rd weeks after the cardiac surgery and third weeks we do echocardiography on all patient. the severity of pericardial effusion will be compared between the two groups

Recruitment status

Recruitment complete

Funding source

Rajaie cardiovascular medical and research center, vice chancellor for research

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060713592N1**

Registration date: **2014-02-11, 1392/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-11, 1392/11/22

Registrant information

Name

Anita Sadeghpour

Name of organization / entity

rajaie cardiovascular medical and research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2145

Email address

Scientific title

Effect of vitamin c and placebo on pericardial effusion in post cardiac surgery patients with or without anticoagulation therapy

Public title

Effect of vitamin c on pericardial effusion in post cardiac surgery patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient 18 years old and older; different cardiac surgery (coronary artery bypass, valvular heart surgery, and simple congenital cardiac surgery). Exclusion criteria: patient who expire at the first day of surgery; patient with history of heart and lung transplantation; complex congenital heart disease surgery.

Age

To **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 400

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ajaei cardiovascular medical and research center

Street address

Niyayesh, Valiasr Ave.

City

Tehran

Postal code

Approval date

2013-06-18, 1392/03/28

Ethics committee reference number

21089

Health conditions studied

1

Description of health condition studied

pericardial effusion

ICD-10 code

I30

ICD-10 code description

Acute pericarditis

Primary outcomes

1

Description

Amount of pericardial effusion

Timepoint

3 weeks

Method of measurement

Quantitative measurements by transthoracic echocardiography

Secondary outcomes

1

Description

The effect of anticoagulation on pericardial effusion and hospital stay

Timepoint

first 3 weeks after cardiac surgery

Method of measurement

Echocardiography and hospital stay after cardiac surgery

Intervention groups

1

Description

Interventiona Group who receive Vit C, The intervention group received vitamin c 1gr intravenously on the day of surgery and 1 g of oral vitamin C daily for 4 days after surgery.

Category

Treatment - Drugs

2

Description

The control group received placebo who given 1gr saline intravenously on the day of surgery and 1 gr of oral placebo daily for 4 days after surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Reseach center

Full name of responsible person

Anita Sadeghpour

Street address

Rajaie Cardiovascular Medical and Reseach center, Niyayesh, Valiasr Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Anita Sadeghpour

Street address

Niyayesh, Valiasr Ave.,

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Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rajaie Cardiovascular Medical and Research Center
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
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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