Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of laboratory findings and clinical outcome of addition of ascorbic acid in prime fluid in patients undergoing CABG

Protocol summary

Study aim
Determining and comparing the clinical and laboratory results of adding ascorbic acid to prime fluid in patients undergoing coronary artery bypass surgery

Design
A randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 110 patients

Settings and conduct
In this triple-blind randomized clinical trial study, 110 eligible patients, referring to Isfahan Chamran Hospital, will be included in the study and will be randomly divided into two groups. Ascorbic acid will be added to the prime solution for patients in the first group and normal saline in the second group. In this study, the patient, the researcher, and the statistical analyst will not have any knowledge of the type of intervention. Then the inflammatory factors and blood parameters of the patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients who are candidates for elective CABG surgery in Chamran Hospital, age category over 35 years, EF over 30%, consent to participate in the study. Exclusion criteria include patients who have other cardiac surgeries at the same time as coronary bypass surgery, having a history of vitamin C use in the last three months, a history of corticosteroid use before hospitalization, having severe kidney or liver failure, re-surgery(, having Drug sensitivity is having a history of celiac disease (due to the effect on vitamin C levels) or malabsorption problems.

Intervention groups
Intervention group: 25 mg/kg of ascorbic acid will be added to the prime solution Control group: 25 mg/kg placebo (normal saline) will be added to the prime solution.

Main outcome variables
Troponin; C-reactive protein (CRP); Ejection fraction (EF), Drainage rate of chest tube

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N75**
Registration date: **2024-10-25, 1403/08/04**
Registration timing: **prospective**

Last update: **2024-10-25, 1403/08/04**
Update count: **0**

Registration date
2024-10-25, 1403/08/04

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

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Iran (Islamic Republic of)

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asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-21, 1403/10/01

Expected recruitment end date
2025-04-20, 1404/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of laboratory findings and clinical outcome of addition of ascorbic acid in prime fluid in patients undergoing CABG

Public title
Evaluation of laboratory findings and clinical outcome of addition of ascorbic acid in patients undergoing coronary artery bypass grafting

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate patients for elective CABG surgery in Chamran Hospital Age category over 35 years EF (ejection fraction) more than 30% Consent to participate in the study

Exclusion criteria:
Patients who have other cardiac surgeries at the same time as coronary bypass surgery History of vitamin C consumption in the last three months History of corticosteroid use before hospitalization Severe renal or hepatic failure Re-surgery Having drug sensitivity Having a history of celiac disease (due to the effect on vitamin C levels) or malabsorption problems

Age
From **35 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 110 eligible patients are randomly selected. For this, the letter A is written on 55 sheets, and the letter B is written on 55 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to achieve the triple-blind study, different doses of ascorbic and placebo (normal saline) will be prepared daily by the operating room nurse (without the researcher's awareness) and placed in the bag and will be labeled A, B will be available to the circulation technician daily (Researcher) is placed. Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2024-08-27, 1403/06/06

Ethics committee reference number
IR.MUI.MED.REC.1403.193

Health conditions studied

1

Description of health condition studied
Coronary artery bypass surgery

ICD-10 code
I25.810

ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s) without angina pectoris

Primary outcomes

1

Description
Troponin

Timepoint
Before and 12 hours after surgery

Method of measurement
Blood test

2

Description
C reactive protein(CRP)

Timepoint
Before and 12 hours after surgery

Method of measurement
Blood test

3

Description
Ejection Fraction (EF)
Timepoint
Before the intervention, at the time of discharge and two weeks after the surgery
Method of measurement
Echocardiography

4

Description
Chest tube drainage rate
Timepoint
After admission to ICU and 2, 4, 6, 12 and 24 hours after surgery
Method of measurement
Measured in milliliters

Secondary outcomes

1

Description
Serum Glutamic Pyruvic Transaminase (SGPT)
Timepoint
Before and 12 hours after surgery
Method of measurement
Blood test

2

Description
serum glutamic-oxaloacetic transaminase (SGOT)
Timepoint
Before and 12 hours after surgery
Method of measurement
Blood test

3

Description
lactate dehydrogenase (LDH)
Timepoint
Before and 12 hours after surgery
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: 25 mg/kg of ascorbic acid will be added to the prime solution.
Category
Treatment - Surgery

2

Description
Control group: 25 mg/kg placebo (normal saline) will be added to the prime solution.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
Alireza Hosseini
Street address
2nd Moshtagh Street, Isfahan.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Alireza Hosseini
Position
Assistant Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available