Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Ascorbic Acid and Grape Seed Extract "Vitis Vinifera L." on Oxidative Stress Induced by on Pump Coronary Artery by Pass Grafting Surgery

Protocol summary

Summary

This study aimed to compare the effect of grape seed extract and ascorbic acid in oxidative stress induced by on pump coronary artery bypass grafting surgery. There are three groups in the study. 75 candidates of coronary artery bypass grafting surgery were randomly assigned to each study group (25 in each group). 1. Control 2. Grape Seed Extract (100 mg/6h - PO, 24h before surgery) 3. Vit C (25 mg/kg in pump circulation during surgery). Inclusion Criteria: Candidates for elective CABG surgery with pump for first time, 3 Vessel Disease (3VD). Exclusion Criteria: High risk patients, Those who need another heart surgery beside CABG, Urgent patients, Diabetics, Ischemic time more than 120 min. We will compare Left Ventricular Ejection Fraction and Total Antioxidant Capacity between groups before and after the interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708271460N1**
Registration date: **2009-02-16, 1387/11/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-02-16, 1387/11/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2008-11-01, 1387/08/11

Expected recruitment end date

2009-03-31, 1388/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ascorbic Acid and Grape Seed Extract "Vitis Vinifera L." on Oxidative Stress Induced by on Pump Coronary Artery by Pass Grafting Surgery

Public title

Comparison of Ascorbic Acid and Grape Seed Extract in Oxidative Stress Induced by on Pump Heart Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Candidates for elective CABG surgery with pump for first time, 3 Vessel Disease (3VD). Exclusion Criteria: High risk patients, Those who need another heart surgery beside CABG, Urgent patients Diabetics, Ischemic time more than 120 min.

Age

No age limit

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
ClinicalTrials.gov
Secondary trial Id
NCT00839085
Registration date
2009-02-06, 1387/11/18

Ethics committees

1

Ethics committee
Name of ethics committee
Regional Ethical Committee of Tabriz University of Medical Sciences
Street address
Daneshgah St,Tabriz University of Medical Sciences
City
Tabriz
Postal code
51656-65811
Approval date
2009-01-05, 1387/10/16
Ethics committee reference number
8710

Health conditions studied

1

Description of health condition studied
Coronary Atrery Bypass Graft (CABG)
ICD-10 code
I20, I21,
ICD-10 code description
Ischaemic heart diseases

2

Description of health condition studied
Atherosclerotic heart disease
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease

3

Description of health condition studied
Ischaemic cardiomyopathy
ICD-10 code
I25.5
ICD-10 code description
Ischaemic cardiomyopathy

Primary outcomes

1

Description
Left Ventricular Ejection Fraction (LVEF)
Timepoint
Before and after CABG
Method of measurement
Trans Thoracic Echocardiography (TTE)

Secondary outcomes

1

Description
Total Antioxidant Capacity (TAC)
Timepoint
Before, middle and after CABG
Method of measurement
Biochemistry (blood sample)

Intervention groups

1

Description
Control Group: without intervention
Category
N/A

2

Description
Grape Seed Extract 100 mg/6h
Category
Treatment - Drugs

3

Description
Vit C 25 mg/kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani Cardiovascular Research Center
Full name of responsible person
Dr Naser Safaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz Univ Med Sci
Full name of responsible person
Vice Chancellor for research (Dr Kazemi)
Street address
Daneshgah St,Tabriz Univ Med Sci
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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
Tabriz Univ Med Sci
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

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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