

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

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Name of organization / entity

Drug Applies Research Center, Tabriz Univ Med Sci

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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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Daneshgah St, Tabriz University of Medical Sciences

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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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Tabriz

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

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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