

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Hossein Babaei

##### Name of organization / entity

Drug Applies Research Center, Tabriz Univ Med Sci

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1336 3311

##### Email address

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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 Artery 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

**Street address**

Daneshgah St, Tabriz University of Medical Sciences

**City**

Tabriz

## 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

**City**

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**

Tabriz Univ Med Sci

**Full name of responsible person**

Naser safaei, MD, Surgeon

**Position**

Associate Prof., MD, Cardiac Surgeon

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Drug Applied Research Center

**Full name of responsible person**

Dr Hossein Babaei

**Position**

Professor of Cardiovascular Pharmacology

**Other areas of specialty/work**

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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*