

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The effect of vitamin C supplement on the level of CK-MB and Troponine enzymes in patients undergoing Coronary Artery Bypass Graft (CABG) surgery

#### Protocol summary

##### Study aim

To determine vitamin C supplementation on cardiac biomarkers (CKMB, CTnT) in patients undergoing CABG (Coronary Artery Bypass Graft).

##### Design

Randomized double-blind clinical trial with two arm parallel groups phase 2-3 trial

##### Settings and conduct

The trial will be conducted at shaheed Rajaei Cardiovascular Medical and Research Center, affiliated to Iran University of Medical Sciences, Iran. All the patients will be screened by an expert cardiologist for eligibility. Those willing to take part in the study will be carefully evaluated with reference to inclusion criteria. Then, they will be requested to sign an informed consent. A third party who is blind to the study will give the sequence extracted from allocation software. After an overnight fasting, blood will be collected and supplements will be provided to the participants. supplementation duration will be 7 days.

##### Participants/Inclusion and exclusion criteria

80 patients' eligible for CABG surgery will be included in the study. Subjects with Valve replacement; chronic renal failure and history of supplementation with recent intake of antioxidants either warfarin will not be included

##### Intervention groups

500 mg vitamin C supplementation will give to individuals in two divided doses for 7 days. In the placebo (control) group, the capsules will contain of maltodextrin.

##### Main outcome variables

serum levels of cardiac markers (CKMB, CTnT)

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180712040438N1**

Registration date: **2018-08-11, 1397/05/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-11, 1397/05/20**

Update count: **0**

#### Registration date

2018-08-11, 1397/05/20

#### Registrant information

##### Name

Jalal Moludi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3335 2148

##### Email address

jmoludi@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-07-23, 1397/05/01

#### Expected recruitment end date

2018-09-23, 1397/07/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of vitamin C supplement on the level of CK-MB and Troponine enzymes in patients undergoing Coronary

Artery Bypass Graft (CABG) surgery

### Public title

Effect of vitamin C supplementation on cardiovascular bio markers in patients undergoing open heart surgery

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

80 patients' eligible for CABG surgery

#### Exclusion criteria:

Recent intake of antioxidants or warfarin  
Valve replacement subjects with body mass index (BMI) above 30  
Kidney disease (creatinine above 1.5)

### Age

No age limit

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Participant
- Care provider
- Investigator

### Sample size

Target sample size: 80

### Randomization (investigator's opinion)

Randomized

### Randomization description

The eligible participants will be randomly allocated to intervention and placebo groups using a software generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout the study.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this double-blind study, no patient and investigator will be aware of the treatment assignments for the duration of the study. For blinding the trial, the tablet and placebo, will be identical in appearance, packaging, and labeling. All capsules will be packed and encoded by the company (Darou Pakhsh Company).

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی و خدمات درمانی تبریز

### Street address

Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

### City

Tabriz

### Province

East Azarbaijan

### Postal code

5166/15731

### Approval date

2018-01-27, 1396/11/07

### Ethics committee reference number

IR.TBZMED.REC.1397.051

## Health conditions studied

### 1

#### Description of health condition studied

سکته قلبی

#### ICD-10 code

I21

#### ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

## Primary outcomes

### 1

#### Description

level of Troponin

#### Timepoint

Baseline and 7 days after intervention

#### Method of measurement

via ELISA kit

### 2

#### Description

level of CK-MB

#### Timepoint

Baseline and 7 days after intervention

#### Method of measurement

via ELISA kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients in this group will receive Vitamin C for 7 days. (a product by darou pakhsh Co. and made in The Iran) and used twice a day.

#### Category

Treatment - Drugs

## 2

### Description

Control group: Patients in this group will receive maltodextrin tablet for 7 days which are same size and shape ( product by darou pakhsh Co. and made in The Iran) and used twice day.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

مرکز آموزشی درمانی شهید رجایی تهران

##### Full name of responsible person

Dr.Ali Sadeghpour

##### Street address

Niayesh St, Rajai Cardiovascular Hospital, Tehran Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

5166614711

##### Phone

+98 21 8897 4463

##### Fax

+98 21 8897 4463

##### Email

jmoludi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Juyban

##### Street address

Vice Chancellor for Research No 2 Central Building,  
Tabriz University of Medical Sciences, Daneshgah  
Street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

##### Phone

+98 41 3335 7581

##### Fax

+98 41 3334 0634

##### Email

jmoludi@yahoo.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor

##### organization/entity?

Yes

##### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Jalal Moludi

##### Position

PhD Candidate

##### Latest degree

Master

##### Other areas of specialty/work

Nutrition

##### Street address

Golgasht St

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

##### Phone

+98 41 3335 2148

##### Fax

+98 41 3335 2148

##### Email

moludij@tbzmed.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Jalal Moludi

##### Position

PhD Candidate

##### Latest degree

Master

##### Other areas of specialty/work

Nutrition

##### Street address

Golgasht St

##### City

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 2148

**Fax**

+98 41 3335 2148

**Email**

moludij@tbzmed.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Jalal Moludi

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Golgasht St

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 2148

**Fax**

+98 41 3335 2148

**Email**

moludij@tbzmed.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

Yes - There is 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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Data collected for the primary outcomes will be shared.

**When the data will become available and for how long**

Accessibility to data is possible 8 months after publication.

**To whom data/document is available**

The data will only be available for people working in academic institutions.

**Under which criteria data/document could be used**

The data of the present study will only be accessible by other researchers, for conducting Meta analysis.

**From where data/document is obtainable**

Jalal Moludi, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, +989399516760, jmoludi@yahoo.com

**What processes are involved for a request to access data/document**

The applicator can send a request to the person responsible for the study by email and within 10 days the document will be sent to the requesting person.

**Comments**