Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 bio-markers (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.
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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

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Niayesh St, Rajai Cardiovascular Hospital, Tehran Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

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

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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 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

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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