Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the effects of whey protein isolate on cardiovascular risk factors and quality of life in patients undergoing coronary artery bypass grafting

Protocol summary

Study aim
Determining the effects of whey protein isolate on cardiovascular risk factors and quality of life in patients undergoing coronary artery bypass grafting

Design
This study is a randomized single-blinded controlled clinical trial with parallel groups. This is a phase 3 trial with sample size of 42. Block randomization is used for the randomization process.

Settings and conduct
In this trial, 42 patients undergoing coronary artery bypass grafting will be selected from Al-Zahra Hospital in Shiraz, based on the inclusion and exclusion criteria. Subsequently, demographic information, smoking status, etc. will be collected from the participants. Following the surgery, their fasting blood sugar, lipid profile and albumin levels will be determined. The MacNew questionnaire will also be filled out for the patients. Then the participants will be divided into two groups receiving whey protein isolate and wheat starch. This trial is a single-blinded study and the intervention will be continued for 14 days. At the end of intervention, the serum markers will be measured again and the MacNew questionnaire will be completed for them.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 30-75 years undergoing coronary artery bypass grafting. Exclusion criteria: undergoing heart surgery for the second time, simultaneous surgeries, ejection fraction <30, patients with renal failure, liver cirrhosis, cancer, metabolic amino acid disorders, malabsorptive syndromes, celiac disease, allergy to dairies, Alzheimer's disease, active infection, pregnancy, lactation, receiving levodopa or albendazole.

Intervention groups
The intervention group will receive whey protein isolate (10 g/d) and the control group will receive wheat starch powder (3 g/d).

Main outcome variables
fasting blood glucose; total cholesterol; triglyceride; HDL-C, LDL-C, albumin, MacNew heart disease quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221022056263N1**
Registration date: **2023-01-14, 1401/10/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-14, 1401/10/24**
Update count: **0**

Registration date
2023-01-14, 1401/10/24

Registrant information
Name
Mahsa Moazen
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-15, 1400/08/24
Expected recruitment end date
2023-12-31, 1402/10/10
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effects of whey protein isolate on cardiovascular risk factors and quality of life in patients undergoing coronary artery bypass grafting

Public title
Effects of whey protein isolate consumption on patients undergoing cardiac surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients who are undergoing coronary artery bypass grafting age 30-75 years
Exclusion criteria:
heart surgery for the second time simultaneous surgeries (such as heart valve surgery) ejection fraction lower than 30 patients with renal failure patients with liver cirrhosis patients with cancer having metabolic amino acid disorders (such as phenylketonuria) patients with malabsorptive syndrome having celiac disease allergy to milk and dairy products patients with Alzheimer's disease patients with active infection pregnant women lactating women receiving levodopa or albendazole medications
Age
From **30 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method is used to assign each participant to the intervention or control group. The participants are randomized with block sizes of 4, so that an equal number of individuals will be assigned to the whey protein or the placebo group. Six possible sequences (including AABB, ABAB, ABBA, BAAB, BABA, BBAA) can be made by this method. Each of the sequences will be randomly selected by numbering them from 1 to 6 and using dice.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study participants are blinded. In fact, whey protein isolate and starch powders are packaged similarly and it is not clear to which of the study groups they belong. The researchers do not also provide any information regarding this issue with the participants.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
School of Nutrition and Food Sciences, Razi Blvd.
City
Shiraz
Province
Fars
Postal code
7554171536
Approval date
2021-08-15, 1400/05/24
Ethics committee reference number
IR.SUMS.REC.1400.427

Health conditions studied

1

Description of health condition studied
patients undergoing coronary artery bypass grafting
ICD-10 code
I25.709
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris

Primary outcomes

1

Description
fasting blood glucose
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
colorimetric method

2

Description
serum triglyceride
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
colorimetric method

3

Description
serum total cholesterol
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
colorimetric method

4

Description
low-density lipoprotein cholesterol (LDL-C)
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
colorimetric method

5

Description
high-density lipoprotein cholesterol (HDL-C)
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
colorimetric method

6

Description
serum albumin
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
colorimetric method

7

Description
Quality of life determined by MacNew questionnaire
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
MacNew Heart Disease health-related quality of life questionnaire

Secondary outcomes

1

Description
Atherogenic Index of plasma
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
logarithm of triglyceride (mmol/l) to high-density lipoprotein cholesterol (mmol/l) ratio

2

Description
total cholesterol to high-density lipoprotein cholesterol (HDL-C) ratio
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
total cholesterol divided by high-density lipoprotein cholesterol

3

Description
low-density lipoprotein cholesterol to high-density lipoprotein cholesterol ratio (LDL-C/HDL-C)
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
low-density lipoprotein cholesterol divided by high-density lipoprotein cholesterol

4

Description
non-high-density lipoprotein cholesterol to high-density lipoprotein cholesterol ratio (non-HDL-C/HDL-C)
Timepoint
Before the start of intervention and 14 days after it
Method of measurement
First of all, high-density lipoprotein cholesterol (HDL-C) is subtracted from total cholesterol to determine non-high-density lipoprotein cholesterol (non-HDL-C). Then, non-HDL-C is divided by HDL-C.

Intervention groups

1

Description
Intervention group: Ten grams of whey protein isolate (once a day) for a period of 14 days will be consumed orally after dissolving in water.
Category
Treatment - Drugs

2

Description
Control group: Three grams of wheat starch powder (once a day) for a period of 14 days will be consumed orally after dissolving in water.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra heart hospital
Full name of responsible person
Maryam Mohammad-Hosseini
Street address
Al-Zahra heart hospital, Sibooye Blvd.
City

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mahtab Memarpour
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Administration Building of Shiraz University of Medical Sciences, Zand Ave.
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Phone
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Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Mohammad-Hosseini
Position
Nutritional expert
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
Unidentifiable data of primary outcomes will be shared.
When the data will become available and for how long
one month following publication of the article
To whom data/document is available
university researchers
Under which criteria data/document could be used
In case of requesting the data for performing secondary studies
From where data/document is obtainable
Mahsa Moazen, School of Nutrition and Food Sciences, Shiraz, Iran +987137251001
What processes are involved for a request to access data/document
Approximately two weeks after the request, data will be provided.
Comments