

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3725 1001

##### Email address

moazen\_m@sums.ac.ir

##### 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, Sibooeye Blvd.

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Shiraz  
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7164954937  
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maryammh63@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr Mahtab Memarpour  
**Street address**  
Administration Building of Shiraz University of Medical Sciences, Zand Ave.  
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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 scientific inquiries

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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**