

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effect of mixed nuts consumption on bio- markers of cardiovascular disease in overweight and obese adults with coronary heart disease

#### Protocol summary

##### Study aim

Effect of mixed nuts consumption on bio markers of cardiovascular disease in overweight and obese adults with coronary heart disease

##### Design

A single center, randomized, not blinded, controlled clinical trial with 2 parallel groups design and 70 participants, started in February and will be continued until may 2020.

##### Settings and conduct

Eligible volunteers will be recruited from Modares hospital. The study is not blinded, randomized clinical trial with two parallel groups. In this study, 70 patients with coronary artery disease referred to the heart clinic, will be randomized into two groups, mixed nuts (20 percent of daily calories) or placebo (5 gram of oat bran) for 8 weeks. Fasting blood sample will be taken at the baseline and the end of study to measure plasma level of lipid profiles, glucose, Insulin, Adiponectin.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Body Mass Index over than 25 kg/m<sup>2</sup>; Willing to participate in the study; Having at least one of the cardiovascular risk factors (diabetes, elevated blood pressure, hyperlipidemia); Age between 35 to 75 years. Exclusion Criteria: Regular consumption of nuts more than 50 grams in a week; Regular consumption (more than once in a week) vitamin and minerals supplements during past month; Having chronic kidney disease

##### Intervention groups

Intervention group: Daily consumption of 20 percent of calories as mixed nuts for 8 weeks. This amount of nuts being given to participants as packaged unsalted and raw nuts including pistachios, almond, peanuts. In addition, subjects of intervention group will be given oat bran powder to be consumed in a daily basis (5 grams/day). Control group: Daily consumption of 5 grams of bran powder (Contain of Oats Bran powder) for 8 weeks

#### Main outcome variables

LDL-cholesterol

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160702028742N6**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **prospective**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

##### Registration date

2020-03-19, 1398/12/29

##### Registrant information

##### Name

Javad Nasrollahzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2236 0656

##### Email address

jnasrolah@razi.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-08, 1399/01/20

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of mixed nuts consumption on bio- markers of cardiovascular disease in overweight and obese adults with coronary heart disease

**Public title**

Effect of nuts consumption on cardiovascular bio- markers

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Body Mass Index over than 25 kg/m2 Willing to participate in the study Having at least one of the cardiovascular risk factors (diabetes, elevated blood pressure, hyperlipidemia) Age between 35 to 75 years

**Exclusion criteria:**

Regular consumption of nuts more than 50 grams in a week Regular consumption (more than once in a week) vitamin and minerals supplements during past month Having chronic kidney disease

**Age**

From **35 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization tool is a sealed envelope. Stratified block randomization will be employed to assign subjects to each of the two groups. Stratification subdivides patients into those with diabetes or without diabetes and in each stratum, blocks of size 4 (two intervention and two control) will be defined and then the patients within each block will be assigned to intervention and control groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of National Nutrition and Food Technology Research Institute

**Street address**

No. 46, West Arghavan Ave., Farahzadi Blvd., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Approval date**

2019-06-22, 1398/04/01

**Ethics committee reference number**

IR.SBMU.NNFTRI.REC.1398.014

**Health conditions studied****1****Description of health condition studied**

Coronary Artery Disease

**ICD-10 code**

I25.1

**ICD-10 code description**

Atherosclerotic heart disease of native coronary artery

**Primary outcomes****1****Description**

fasting plasma insulin

**Timepoint**

Baseline and the end of the study

**Method of measurement**

Elisa

**Secondary outcomes****1****Description**

Fasting plasma LDL-cholesterol

**Timepoint**

Baseline and the end of the study

**Method of measurement**

Plasma level, Enzymatic

**2****Description**

Fasting blood sugar

**Timepoint**

Baseline and the end of the study

**Method of measurement**

Serum level, Enzymatic method

## Intervention groups

### 1

#### Description

Intervention group: Daily consumption of 20 percent of calories as mixed nuts for 8 weeks. This amount of nuts being given to participants as packaged unsalted and raw nuts including pistachios, almond, peanuts. Oat bran in amount of 5 g/day will also be consumed by patients of this group.

#### Category

Lifestyle

### 2

#### Description

Control group: Daily consumption of 5 grams of Bran powder (Contain of Oats Bran powder) for 8 weeks

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Modares Medical andzxr Research Center

##### Full name of responsible person

Dr Saeed Alipour Parsa

##### Street address

Modares Hospital, Sadat Abad intersection, Yadegar Emam Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1998734383

##### Phone

+98 21 2207 4087

##### Email

s\_alipour@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Afshin Zarghi

##### Street address

No. 46, Hafezi street, Farahzadi blvd, Qods Town, Tehran

##### City

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##### Province

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##### Postal code

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##### Phone

+98 21 2236 0658

##### Email

jnasrollahzadeh@gmail.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Matin Ghanavati

##### Position

Ph.D Student in Nutrition Sciences

##### Latest degree

Master

##### Other areas of specialty/work

Nutrition

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No. 46, Hafezi street, Farahzadi blvd, Qods Town, Tehran

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##### Postal code

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##### Phone

+98 21 2236 0658

##### Email

ghanavati.matin@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Javad Nasrollahzadeh

##### Position

Assistant Professor

##### Latest degree

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Matin Ghanavati

**Position**

Ph.D. Student in Nutrition Sciences

**Latest degree**

Master

**Other areas of specialty/work**

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**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no reason

**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**

No - There is not 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**

No - There is not a plan to make this available