Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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/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

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
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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
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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
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Modares Hospital,Sadat Abad intersection, Yadegar Emam Highway, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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No. 46, Hafezi street, Farahzadi blvd, Qods Town, Tehran
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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
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
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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)
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