Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Cashew consumption on lipid profile, Apo B, Apo A-I, hs-CRP and Paraoxonase-1 in patients with type 2 diabetes.

Protocol summary

Summary

The aim of this study is to investigate the effect of Cashew Consumption on lipid profile, Apo B, Apo A-I, hs-CRP, and Paraoxonase-1 in type 2 diabetic patients. In this parallel group, randomized controlled trial, 50 men and women with type 2 diabetes aged 35-70 years old will be recruited from Iranian Diabetes Society. The study will be explained to each participant to sign informed consent. Prior to the study, the subjects will be required to complete 3-days 24-hour dietary recall. Diets will be analyzed for calorie and macronutrients content. Then, we will substitute 10% of usual daily calorie intake with Cashew in intervention group. The control group will follow their habitual diet. Blood samples will be obtained after an overnight fasting before and after the study. All anthropometric and physical activity variables will be measured both before and after the trial. Diets and medications dosage will be held constant throughout the study and each subject's exercise level will be kept constant and monitored by physical activity questionnaires (IPAQ).Compliance will be assessed from 3-days 24-recalls which obtain at first, in the middle and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812252709N5**
Registration date: **2010-03-16, 1388/12/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-03-16, 1388/12/25

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8862 2755

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Recruitment status

Recruitment complete

Funding source

Research Institute for Islamic & Complementary Medicine

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Cashew consumption on lipid profile, Apo B, Apo A-I, hs-CRP and Paraoxonase-1 in patients with type 2 diabetes.

Public title

Effect of Cashew consumption on lipid profile in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being volunteer or willingness to attend, age 35-70 years old, confirmed type 2 diabetes for at least 1 year (FPG ≥ 126 mg/dl or 2hPG ≥ 200 mg/dl), BMI ≤ 35 kg/m2, TG < 400 mg/dl, HbA1C < 9%,

LDL ≤ 200 mg/dl, Blood pressure ≤160/90 mmHg
Exclusion criteria: Allergy to nuts, insulin consumption, Smoking cigarette, drinking alcohol or drug abuse, Diabetic nephropathy or retinopathy, History of stroke or heart attack, Thyroid disease, Following vegetarian or weight-reducing diets 2 months prior to the study, Eating nuts > 2 times/wk at least 2 months prior to the study, Changing medication dosage or physical activity level 2 months before or during the study

Age
From **35 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Research Institute for Islamic & Complementary Medicine

Street address
No.9, Pirnia Alley, Lalehzar Ave, Jomhouri-Ye-Eslami Ave.

City
Tehran

Postal code

Approval date
2010-04-12, 1389/01/23

Ethics committee reference number
244/پ26/م/ط

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes, Diabetic dyslipidemia

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Low Density Lipoprotein (LDL-C)

Timepoint
8 weeks

Method of measurement
Laboratory kit

2

Description
Total Cholesterol (TC)

Timepoint
8 weeks

Method of measurement
Friedewald equation

3

Description
Triglyceride (TG)

Timepoint
8 weeks

Method of measurement
Laboratory kit

4

Description
High Density Lipoprotein (HDL-C)

Timepoint
8 weeks

Method of measurement
Laboratory kit

5

Description
TC/HDL-C ratio

Timepoint
8 weeks

Method of measurement
calculation

6

Description
LDL-C/HDL-C ratio

Timepoint
8 weeks

Method of measurement
calculation

7

Description

Apo A-I
Timepoint
8 weeks
Method of measurement
immunoturbidimetry

8

Description
Apo B-100
Timepoint
8 weeks
Method of measurement
immunoturbidimetry

9

Description
Paraoxonase-1
Timepoint
8 weeks
Method of measurement
spectrophotometry

10

Description
Fasting Blood Sugar (FBS)
Timepoint
8 weeks
Method of measurement
Enzymatic

11

Description
Fasting Insulin
Timepoint
8 weeks
Method of measurement
Enzymatic

12

Description
Total Antioxidant Capacity (TAC)
Timepoint
8 weeks
Method of measurement
Ferric reducing ability of plasma (FRAP)

13

Description
High sensitivity C-reactive protein (hs-CRP)
Timepoint
8 weeks
Method of measurement
immunoturbidimetry

14

Description
Blood pressure
Timepoint
8 weeks
Method of measurement
sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: Cashew Consumption (10% of daily total calorie intake), 1 time/day, for 2 month
Category
Treatment - Other

2

Description
Control: No intervention for this group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian Diabetes Society
Full name of responsible person
Dr. Asadollah Rajab
Street address
No. 46, Ramin malakuti Ave, Patris lumumba Ave, Sattarkhan Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Institute for Islamic & Complementary Medicine
Full name of responsible person
Dr. Ashrafedin Gushegir
Street address
No.9, Pirnia Alley, Lalehzar Ave, Jomhouri-Ye-Eslami Ave.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Research Institute for Islamic & Complementary Medicine

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Farzad Shidfar

Position

Associate professor

Other areas of specialty/work

Street address

Next to Milad hospital, Between Chamran & Sheikh Fazlollah Nouri highway, Hemmat highway.

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Person responsible for scientific inquiries

Contact

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Iran University of Medical Sciences

Full name of responsible person

Dr. Farzad Shidfar

Position

Associate Professor

Other areas of specialty/work

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Fax

Email

shidfar44@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty