Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of hazelnut 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 Hazelnut Consumption on lipid profile, Apo B, Apo A-I, hs-CRP and Paraoxonase-1 in type 2 diabetic patients. In this parallel randomized controlled trial, 50 men and women with type 2 diabetes will be recruited from Institute of Endocrinology & Metabolism of Iran University of Medical Sciences. The subjects will be 35-70 y of age. Inclusion criteria are BMI≤35 kg/m2, TG<400 mg/dl, HbA1C<9%, LDL≤200 mg/dl and Blood pressure ≤ 160/90 mmHg . Exclusion criteria are known allergy to nuts, taking insulin, smoking cigarettes, following vegetarian or weigh-reducing diets. The study will be explained to each subject, who signs an 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 hazelnut in intervention group. The control group will follow their habitual diet. Blood samples will be obtained after an overnight fast before and after the study. All anthropometric and physical activity variables will be measured both before and after the trial. Compliance will be assessed from 3-days 24-recalls which obtain at first, in the middle and at the end of the study. 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).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807262602N1**
Registration date: **2009-12-02, 1388/09/11**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2009-12-02, 1388/09/11

Registrant information

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Shahryar Eghtesadi
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Iran university of Medical Sciences

Expected recruitment start date

2009-12-01, 1388/09/10

Expected recruitment end date

2010-03-06, 1388/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Effect of hazelnut consumption on lipid profile in diabetic patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Being volunteer or Wishing to attend, 35-70 y old, diagnosed with 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, Taking insulin, Smoking cigarette, drinking alcohol or drug abuse, Following vegetarian or weight-reducing diet 2 months before the study, Diabetic nephropathy or retinopathy, History of stroke or heart attack, Thyroid disease, Eating nuts > 2 times/wk at least 2 months before the study, Changing medication dosage or physical activity level 2 mo 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
School of Health. Iran University of Medical Sciences
Street address
School of Health, Alvand Ave, Arjanteen Square
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
2155/5پ/26/د

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes, Diabetic Dyslipidemia
ICD-10 code
E10, E11,
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Decrease Total Cholesterol (TC)
Timepoint
8 weeks
Method of measurement
Friedewald equation

2

Description
Decrease Low Density Lipoprotein (LDL-C)
Timepoint
8 week
Method of measurement
Laboratory kit

3

Description
Decrease Triglyceride (TG)
Timepoint
8 weeks
Method of measurement
Laboratory Kit

4

Description
Increase High Density Lipoprotein (HDL-C)
Timepoint
8 weeks
Method of measurement
Laboratory kit

5

Description
Decrease TC/HDL-C ratio
Timepoint
8 weeks
Method of measurement
calculation

6

Description
Decrease LDL-C/HDL-C ratio
Timepoint
8 weeks
Method of measurement

Calculation

7

Description
Increase Apo A-I
Timepoint
8 weeks
Method of measurement
immunoturbidimetry

8

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

9

Description
Increase Paraoxonase-1
Timepoint
8 weeks
Method of measurement
spectrophotometry

10

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

11

Description
Decrease Fasting Insulin
Timepoint
8 weeks
Method of measurement
Enzymatic

12

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

13

Description
Decrease high sensitivity C-reactive protein (hs-CRP)
Timepoint
8 weeks
Method of measurement
Immunoturbidimetry

14

Description
Decrease blood pressure
Timepoint
8 weeks
Method of measurement
sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: Hazelnut 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
Institute of Endocrinology & Metabolism of Iran University of Medical Sciences
Full name of responsible person
Street address
City

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Mohsen Asadi Lari
Street address
Hemmat high Way
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences

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
School of Health, Iran University of Medical Sciences
Full name of responsible person
Dr. Shahriar Eghtesadi
Position
Full Professor
Other areas of specialty/work
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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