

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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 \leq 35 kg/m², TG<400 mg/dl, HbA1C<9%, LDL \leq 200 mg/dl and Blood pressure \leq 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

Name

Shahryar Eghtesadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 9118

Email address

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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 \geq 126 mg/dl or 2hPG \geq 200 mg/dl), BMI \leq 35 kg/m², TG < 400 mg/dl, HbA1C < 9%, LDL \leq 200 mg/dl, Blood pressure \leq 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

Other areas of specialty/work**Street address**

School of Health, Alvand Ave, Arjanteen Square

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Tehran

Postal code**Phone**

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Fax**Email**

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Web page address**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**Street address**

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Full name of responsible person

Dr Shahriar Eghtesadi

Position

Full Professor

Person responsible for updating data**Contact****Name of organization / entity****Full name of responsible person**

Dr Shahriar Eghtesadi

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address****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