

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effects of pomegranate seed oil on insulin resistance, serum concentrations of systemic and vascular inflammatory markers, adipokines and lipid profile in type 2 diabetic patients

Protocol summary

Summary

The present study has been designed to investigate the effects of pomegranate seed oil (PSO) on insulin resistance, serum concentrations of systemic and vascular inflammatory markers, adipokines and lipid profile in type 2 diabetic patients. It is a randomized, double-blind and placebo-controlled trial. Eighty subjects are recruited from an endocrine clinic sequentially and randomly assigned into two groups, the intervention (n = 40) and control (n = 40) groups. For all of whom demographic data and medical history at baseline will be documented, and subjects will be given capsules containing either PSO or placebo for eight weeks. The intervention group will consume PSO capsules, containing 1000 mg PSO twice daily (2000 mg PSO), while controls will take placebo capsules for eight weeks. Inclusion criteria are: willingness to work; diabetes type 2 (for 5 to 10 years); age between 35 and 65 years; BMI between 20 to 30. Exclusion criteria are: supplementation with antioxidant and anti-inflammatory drugs during the past month; weight loss diets; not medication compliance; patient with severe hyperglycemia (fasting glucose greater than 250); renal failure; heart disease and liver failure. At the beginning and end of intervention after 12 to 14 hours of fasting, 10 ml of blood is taken from each patient. HbA1C levels will be measured by ion-exchange chromatography. Insulin, adiponectin, leptin, systemic inflammation, and vascular factors (including IL-6, hs-CRP, sICAM-1, sVCAM-1) will be determined by ELISA, serum triglyceride, total cholesterol, HDL-C and LDL-C will be measured enzymatically using autoanalyzer. Nutrition program and SPSS version 18 will be used respectively for dietary assay and analyzing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409031640N15**

Registration date: **2015-05-16, 1394/02/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name

Parvin Mirmiran

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Me

Country

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute Endocrine and Metabolism Research Center, Isfahan university of Medical Sciences, Isfahan, Iran

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of pomegranate seed oil on insulin resistance, serum concentrations of systemic and vascular inflammatory markers, adipokines and lipid profile in type 2 diabetic patients

Public title

Effects of pomegranate seed oil in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : willingness to work diabetes type 2 (for 5 to 10 years) ;35 to 65 years of age;BMI between 20to30. Exclusion criteria: supplementation with antioxidant and anti-inflammatory drugs during the past month;weight-loss diets;not medication compliance; patient having severe hyperglycemia (fasting glucose greater than 250); renal failure; heart disease; liver failure

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical committee,National Nutrition and Food technology Institiute

Street address

National Nutrition and Food technology Institiute, Shahid hafezi street, Shahrak garb, Farahzadi Avenue, Tehran, Iran

City

Tehran

Postal code

19819619573

Approval date

2013-12-08, 1392/09/17

Ethics committee reference number

051526

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

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

fasting blood glucose

Timepoint

Begining and the end

Method of measurement

Enzymatic

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

total cholestrol

Timepoint

begining and the end of study

Method of measurement

enzymatically using autoanalyze

Intervention groups**1****Description**

Intervention group: Pomegranate seed oil capsule, containing 1000 mg PSO, twice daily (2000 mg PSO) for 8 weeks

Category

Treatment - Drugs

2**Description**

Control group:placebo capsules twice daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrine&Metabolism Research Center

Full name of responsible person

Dr.Elham faghihimani

Street address

Sedigheh Tahereh Research Complex, Khorram
Street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Institute

Full name of responsible person

Dr.Parvin Mirmiran

Street address

National Nutrition and Food Technology Institute,
Shahid Hafezi street, Shahrak Garb, Farahzadi
Avenue,Tehran, Iran

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Tehran

Grant name

18

Grant code / Reference number

384

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

Yes

Title of funding source

National Nutrition and Food Technology Institute

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Isfahan endocrine&Metabolism Research Center

Full name of responsible person

Dr. Elham Faghihimani

Street address

Sedigheh Tahereh Research Complex, Khorram
Street, Isfahan, Iran

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Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Isfahan endocrine&Metabolism Research Center

Proportion provided by this source**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

National Nutrition and Food Technology Institute

Full name of responsible person

Dr.Parvin mirmiran

Position

PHD of nutrition

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

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Postal code

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