

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of effects of pomegranate seed oil on lipid profiles, apolipoproteins and body composition in subjects with low HDL-C concentrations

#### Protocol summary

##### Summary

The present study has been designed to investigate the effect of pomegranate seed oil (PSO) treatment on lipid profiles, apolipoproteins and body composition of subjects with low serum HDL-C levels. The study has a parallel, randomized, double-blind and placebo-controlled design. One hundred and fifty subjects with low HDL-C levels (serum HDL-C < 40 mg/dl) will be recruited from endocrine clinics using a sequential design and randomly assigned into 3 groups, 1600 mg PSO (n =50), 3200 mg PSO (n =50) and placebo (n =50) groups. For every patient, medical history including history of medication use will be obtained and a thorough physical examination will be performed. All subjects will be given capsules for twelve weeks. The 1600 mg PSO group will consume 2 PSO (800 mg PSO) capsules and 2 placebo capsules, The 3200 mg PSO group will consume 4 PSO capsules daily, while controls will take 4 placebo capsules. Measurements of anthropometric indexes, body composition, and blood pressure will be obtained at baseline and again 12 weeks after treatment. Physical activity and 3 consecutive dietary recalls will be obtained at baseline, and at the end of the weeks 6 and 12. After 12 to 14 hours overnight fasting, blood samples will be taken for biochemical analysis in days 1, 2 and at the end of weeks 2, 4, 8 and 12. Measurement of serum cholesterol, triglycerides, LDL-C, HDL-C, HDL-C2, HDL-C3, VLDL-C, Apo B100, Apo AI, Panicle acid and 9c, 11t CLA will be done in each sample.

#### General information

##### Acronym

pomegranate seed oil (PSO)

##### IRCT registration information

IRCT registration number: **IRCT201107201640N5**

Registration date: **2011-09-29, 1390/07/07**  
Registration timing: **registered\_while\_recruiting**

Last update:  
Update count: **0**

**Registration date**  
2011-09-29, 1390/07/07

##### Registrant information

###### Name

Parvin Mirmiran

###### Name of organization / entity

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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2243 2500

###### Email address

mirmiran@endocrine.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Obesity Research Center, Research Institute for Endocrine Science, Shaheed Beheshti University of Medical Sciences

##### Expected recruitment start date

2011-04-16, 1390/01/27

##### Expected recruitment end date

2011-12-18, 1390/09/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Evaluation of effects of pomegranate seed oil on lipid profiles, apolipoproteins and body composition in subjects with low HDL-C concentrations

**Public title**

Evaluation of effects of pomegranate seed oil on lipid profiles, apolipoproteins and body composition in subjects with low HDL-C concentrations

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: willingness to cooperate; ages 20-70 years; those with  $35 \leq \text{BMI (kg/m}^2) \leq 25$ ; having levels of HDL-C  $< 40 \text{ mg/dl}$  in the last 12 months; Who are placed in stage I and stage II on TLC, according to NCEP ATP III criteria; Diabetic people not used Glitazones and insulin or consume constantly oral diabetes medications for at least three months Even if taking anti-lipid medications (statins and fibers); Lack of breastfeeding and pregnancy; Those who have had less than 5 Kg in body weight in the last 3 months; Not having any thyroid disorders and kidney failure; Lack of any severe mental illness; Not having cancer in the past five years; Lack of peptic ulcer disease; No smoking and alcohol; Not using drugs affecting lipid profile such as corticosteroids, cyclosporine, propranolol and glucocorticoid. Exclusion criteria: weight loss  $> 10 \text{ Kg}$  during the study, Diagnosis of any of the diseases mentioned in inclusion criteria, during the study; Patient's lack of cooperation in each of the stages studied.

**Age**

From **20 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**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**

Research Institute for Endocrine Science, Shaheed Beheshti University of Medical Sciences

**Street address**

No.24, Parvaneh St, Yemen Blvd, Chamran highway

**City**

Tehran

**Postal code****Approval date**

2011-06-03, 1390/03/13

**Ethics committee reference number**

EC353

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

low HDL-C concentrations

**ICD-10 code**

E78

**ICD-10 code description**

Disorders of lipoprotein metabolism and other lipidaemias

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

low HDL-C

**Timepoint**

baseline and end of weeks 2, 4, 8 and 12.

**Method of measurement**

Enzymatic colorimetric method and sediment specific

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

body weight

**Timepoint**

at the start and end of the 12 weeks study.

**Method of measurement**

anthropometric measurements

**2****Description**

blood pressure

**Timepoint**

at the start and end of the 12 weeks study

**Method of measurement**

blood pressure measurement

**Intervention groups****1**

Description

The 1600 mg PSO group: 2 PSO (800 mg PSO) capsules and 2 placebo capsules.

**Category**

Treatment - Other

**2**

**Description**

The 3200 mg PSO group: 4 PSO capsules daily.

**Category**

Treatment - Drugs

**3**

**Description**

Control group: 4 placebo capsules.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Lipid Clinic of shahid Rajai Heart Hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

**2**

**Recruitment center**

**Name of recruitment center**

endocrine clinice of Talaghani Hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

**3**

**Recruitment center**

**Name of recruitment center**

Iran Diabetes Association

**Full name of responsible person**

**Street address**

**City**

Tehran

**4**

**Recruitment center**

**Name of recruitment center**

Research Institue for Endocrine Science, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Research Institute for Endocrine Science, Shaheed Beheshti University of Medical Sciences

**Full name of responsible person**

Parvin Mirmiran

**Street address**

No.24, Parvaneh St, Yemen Blvd, Chamran highway

**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 Endocrine Science, Shaheed Beheshti 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**

Obesity Research Center, Research Institue for Endocrine Science, Shaheed Beheshti University of Med

**Full name of responsible person**

Parvin Mirmiran

**Position**

Director of Nutrition Unit of Obesity Research Center/ PhD in Nutrition

**Other areas of specialty/work**

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**Web page address**

**Person responsible for scientific**

## **inquiries**

### **Contact**

#### **Name of organization / entity**

Obesity Research Center, Research Institute for  
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Med

#### **Full name of responsible person**

Parvin Mirmiran

#### **Position**

PhD in Nutrition

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## **Person responsible for updating data**

### **Contact**

#### **Name of organization / entity**

obesity research center, research institute for  
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#### **Full name of responsible person**

Golaleh Asghari

#### **Position**

MSc in Nutrition

#### **Other areas of specialty/work**

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#### **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*