

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

Street address

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

City

Tehran

Postal code

Phone

+98 21 2243 2500

Fax

Email

mirmiran@endocrine.ac.ir

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Parvin Mirmiran

Position

PhD in Nutrition

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 21 2243 2500

Fax

Email

mirmiran@endocrine.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

obesity research center, research institute for
endocrine science, shaheed beheshti university of me

Full name of responsible person

Golaleh Asghari

Position

MSc in Nutrition

Other areas of specialty/work

Street address

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

City

Tehran

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