Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

effect of pomegranate seed oil on hyperlipidemic subjects: a double-blind placebo-controlled clinical trial

Protocol summary

Summary

The present study has been designed to investigate the effect of PSO supplementation on lipid profiles of hyperlipidemic subjects. The study has a randomized, double-blind and placebo-controlled design. Sixty-six hyperlipidemic subjects (serum cholesterol > 200 mg/dl and serum triglycerides > 150 mg/dl) are to be recruited from an endocrine clinic using a sequential clinical trial design and randomly assigned into groups, the PSO (n =33) and placebo (n =33) 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 four weeks. The PSO group will consume PSO capsules, containing 400 mg PSO twice daily (800 mg PSO), while controls will take placebo capsules with the same dosage. Measurements of anthropometric indexes, body composition, blood pressure and physical activity, and 3 consecutive dietary recalls will be obtained at baseline and 4 weeks after supplementation. At baseline and after 4 weeks, medication and supplement use will be recorded in a questionnaire, and for biochemical measurements, after 12 to 14 hours overnight fasting, blood samples will be taken for biochemical analysis, including cholesterol, triglycerides, LDL-C, HDL-C, ox-LDL, insulin and of fasting plasma samples.

General information

Acronym

effect of pomegranate seed oil on hyperlipidemia

IRCT registration information

IRCT registration number: **IRCT138711151640N1**
Registration date: **2009-07-16, 1388/04/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-07-16, 1388/04/25

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

1- Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University (M.C), Tehran, I.R. Iran 2-Department of Medicinal Chemistry, Faculty of Pharmacy and Pharmaceutical Sciences Research Center, Tehran University (M.C), Tehran, I.R. Iran.

Expected recruitment start date

2008-10-01, 1387/07/10

Expected recruitment end date

2009-03-20, 1387/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of pomegranate seed oil on hyperlipidemic subjects: a double-blind placebo-controlled clinical trial

Public title

pomegranate seed oil study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: serum cholesterol concentrations > 200 mg/dl , serum triglyceride concentration > 150 mg/dl, age more than 20 years, body mass index ≤ 35 kg/m2 Exclusion criteria: being pregnant or lactating, diagnosed allergy and liver dysfunction

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: **66**

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 ethical committee of Research Institute for Endocrine Sciences of Shahid Beheshti Universit

Street address

No 24, Parvaneh street, Yemen Ave., Velenjak

City

Tehran

Postal code

19395-4763

Approval date

2008-07-07, 1387/04/17

Ethics committee reference number

50963

Health conditions studied

1

Description of health condition studied

hyperlipidemia

ICD-10 code

E78

ICD-10 code description

Disorders of lipoprotein metabolism and other lipidaemias

Primary outcomes

1

Description

lipid profile concentration

Timepoint

1 month

Method of measurement

biochemical measurements on blood sample

Secondary outcomes

1

Description

hyperlipidemia

Timepoint

1 month

Method of measurement

biochemical measurements on blood sample

Intervention groups

1

Description

Pomegranate seed oil capsule, containing 400 mg PSO, twice daily (800 mg PSO) for 4 weeks

Category

Treatment - Drugs

2

Description

Placebo capsule

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and metabolism clinic, Erfan hospital

Full name of responsible person

Street address

Riazi Bakhshayesh street, Kaj square, Saadat-abad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University (M.C)

Full name of responsible person

Dr. Parvin Mirmiran

Street address

No 24, Parvaneh street, Yemen Ave., Velenjak

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University (M.C)

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

Pharmaceutical Sciences Research Center, Faculty of Pharmacy , Tehran University (M.C)

Full name of responsible person

Dr. Abbas Shafie - Dr. Mohammadreza Fazeli

Street address

Poorsina street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmaceutical Sciences Research Center, Faculty of Pharmacy , Tehran University (M.C)

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

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University (M.C)

Full name of responsible person

Dr. Parvin Mirmiran

Position

Director of nutrition unit / PhD in nutrition

Other areas of specialty/work

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Person responsible for updating data

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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