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

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
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
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 Shafei - 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

Street address
No 24, Parvaneh street, Yemen Ave., Velenjak

City
Teharn

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 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

Street address
No 24, Parvaneh street, Yemen Ave., Velenjak

City
Teharn

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 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

Street address
No 24, Parvaneh street, Yemen Ave., Velenjak

City
Tehran
Postal code
Phone
+98 21 2243 2500
Fax
Email
mirmiran@endocrine.ac.ir
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