

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Effect of two types of high protein diet on component of metabolic syndrome, insulin resistance and inflammatory markers in women with polycystic ovary syndrome

Protocol summary

Summary

The objective of this study is to investigate the effects of two types of high protein diet on lipid profile and inflammatory markers in polycystic ovary syndrome (PCOS) patients. This randomized crossover, controlled clinical trial includes 30 patients with PCOS. Exclusion criteria were considered any change in lifestyle during interventions and new case of PCOS that using drug for treatment. Participants were randomly assigned to consume a control diet (containing 30% fat, 30% protein and 40% carbohydrate) with animal protein; in intervention diet animal protein (7ser/wk) in the diet (containing 30% fat, 30% protein and 40% carbohydrate) was replaced by plant protein, each for 8 weeks. Total cholesterol (TC), triglyceride concentration (TG), LDL-C, HDL-C, interleukin 6 and c reactive protein (CRP) was calculated as cardiovascular risk factors parameters, at baseline and 8 weeks after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307211640N11**
Registration date: **2013-08-03, 1392/05/12**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-03, 1392/05/12

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)

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Recruitment status

Recruitment complete

Funding source

Research Institute for endocrine sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of two types of high protein diet on component of metabolic syndrome, insulin resistance and inflammatory markers in women with polycystic ovary syndrome

Public title

Effect of diet therapy in polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: using contraceptive pill and metformin during last 3 months; no change in weight during last 3 months; not having specific diet; body mass index between 25-30 kg/m² and having polycystic ovary syndrome (pocs). Exclusion criteria: change in lifestyle and new case of pcos that using drug for treatment.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute for Endocrine Sciences

Street address

No 24, A'rabi Av, Yeman st, Velenjak

City

Tehran

Postal code

Approval date

2013-07-23, 1392/05/01

Ethics committee reference number

929/409

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovary syndrome

Primary outcomes

1

Description

lipid profile

Timepoint

2 month after intervention

Method of measurement

kit

2

Description

inflammatory markers

Timepoint

2 month after intervention

Method of measurement

kit

Secondary outcomes

1

Description

weight

Timepoint

2 month after intervention

Method of measurement

scale

Intervention groups

1

Description

in intervention diet animal protein (7ser/wk) in the diet (containing 30% fat, 30% protein and 40% carbohydrate) was replaced by plant protein

Category

Lifestyle

2

Description

control diet (containing 30% fat, 30% protein and 40% carbohydrate) with animal protein

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute for Endocrine Sciences

Full name of responsible person

Street address

No 24, A'rabi Av, Yeman st, Velenjak

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Institute for endocrine sciences

Full name of responsible person
Davod Khalili

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No 24, A'rabi St, Yeman St, Velenjake

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 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
Research Institute for Endocrine Sciences

Full name of responsible person
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Position
Ph.D

Other areas of specialty/work

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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