Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Phone

+98 21 2243 2500

Email address

mirmiran@endocrine.ac.ir

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 polycystice overy syndrome

Public title

Effect of diet therapy in polycystic overy syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inculsion criteria: using conraceptive 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 polysystic overy syndrome (pocs). Exculsion criteria: change in lifestyle and new case of pcos that using drug for treatmen.

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
Polycystice overy syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystice overy 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 siences
Full name of responsible person
Davod Khalili
Street address
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 siences
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
Parvain Mirmiran
Position
Ph.D
Other areas of specialty/work
Street address
24 No, A'rabi Av, Yeman St, Velenjake
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
Research Institute for Endocrine Sciences
Full name of responsible person
Parvin Mirmiran
Position
Ph.D
Other areas of specialty/work
Street address
24 No, A'rabi Av, Yeman ST, Velenjak
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
Research Institue for Endocrine Sciences
Full name of responsible person
Parvin Mirmiran
Position
Ph.D
Other areas of specialty/work
Street address
No. 24, A'rabi Av, Yeman St, Velenjak
City
Tehran
Postal code
19395-4763
Phone
+98 21 2243 2500
Fax
+98 22402463
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