

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Clinical trial of the effect of soy intake compared with the control diet on metabolic profiles in patients with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of soy intake on metabolic profiles in patients with polycystic ovary syndrome.

Design

Study design: Parallel randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 60 patients with polycystic ovary syndrome of eligible and referred to Akbarabadi Hospital affiliated to Iran University of Medical Sciences, Tehran, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria and aged 18 to 40 years will be included in this study. Exclusion criteria: Pregnant women Hyperprolactinaemia Thyroid dysfunction Endocrine diseases including diabetes, impaired glucose tolerance and gastrointestinal problems Took medications, such as hormonal contraceptives, insulin sensitising agents, anti-inflammatory or antidiabetic and lipid lowering drugs, or any other medications that might affect reproductive physiology during the 8-week intervention.

Intervention groups

Intervention: Patients will be assigned to receive either soy plus low calorie diet (n=30) or control plus low calorie diet (n=30).

Main outcome variables

Insulin metabolism (primary outcomes), lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201701295623N104**

Registration date: **2017-02-01, 1395/11/13**

Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**

Update count: **1**

Registration date

2017-02-01, 1395/11/13

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-01-17, 1395/10/28

Expected recruitment end date

2017-01-24, 1395/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of soy intake compared with the

control diet on metabolic profiles in patients with polycystic ovary syndrome

Public title

Effect of diet therapy in treatment of patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18–40 years old Patients with PCOS according to Rotterdam criteria

Exclusion criteria:

Pregnant women Hyperprolactinaemia Thyroid dysfunction Endocrine diseases including diabetes, impaired glucose tolerance and gastrointestinal problems Took medications, such as hormonal contraceptives, insulin sensitising agents, anti-inflammatory or antidiabetic and lipid lowering drugs, or any other medications that might affect reproductive physiology during the 8-week intervention.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either soy supplements (n=30) or placebo (n=30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Vice chancellor for research, Iran University of

Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2017-01-16, 1395/10/27

Ethics committee reference number

IR.IUMS.REC.1395.26552

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Using HOMA formula

3

Description

Insulin sensitivity

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Using QUICKI formula

Secondary outcomes

1

Description

Hs-CRP

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

2

Description

HDL

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

Triglycerides

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Total cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

Total antioxidant

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

7

Description

Glutathione

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

8

Description

Nitric oxide

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Soy-protein diet, 0.8 g/kg protein (35% animal protein, 35% soy protein, and 30% other vegetable proteins), daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Standard diet, 0.8 g/kg protein (70% animal and 30% vegetable proteins), daily for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Clinic

Full name of responsible person

Maryam Karamali

Street address

Akbarabadi Hospital, Mowlavi Street, Tehran

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Province

Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of

Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi

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Email

mosavi-sj@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available