

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1534 3570

###### Email address

asemi\_z@kaums.ac.ir

##### 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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8612780660

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dr.karamali@arakmu.ac.ir

**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

**Street address**

Vice chancellor for research, Iran University of  
Medical Sciences, Hemmat Highway, Tehran

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**Province**

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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

**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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