Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Clinical trial of the effect of soy isoflavone supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Protocol summary

Study aim
The aim of this study is to determine the effects of soy isoflavone supplementation on hormonal profiles in patients with polycystic ovary syndrome (PCOS).

Design
Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct
Population and sample size: 70 patients with PCOS of eligible and referred to Kosar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with PCOS according to Rotterdam criteria, higher than 5 years of their disease and aged 18 to 40 years will be included in this study. Exclusion criteria: Pregnant women Elevated levels of prolactin Thyroid disorder Endocrine diseases including diabetes or impaired glucose tolerance, and gastrointestinal problems

Intervention groups
Intervention: Patients will be assigned to receive either soy isoflavone supplements (intervention group: n=35) or placebo (control group: n=35).

Main outcome variables
Outcomes: Markers of insulin resistance and androgens (primary outcomes) and biomarkers of oxidative stress and other metabolic profiles (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT201601025623N62**
Registration date: **2016-01-12, 1394/10/22**
Registration timing: **retrospective**

Last update: **2019-09-20, 1398/06/29**
Update count: **1**

Registration date
2016-01-12, 1394/10/22

Registrant information

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Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date
2015-11-12, 1394/08/21
Expected recruitment end date
2015-11-29, 1394/09/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Clinical trial of the effect of soy isoflavone supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Public title
Effect of supplementation in treatment of women with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with PCOS according to Rotterdam criteria Aged 18 to 40 years
Exclusion criteria:
Pregnant women Elevated levels of prolactin Thyroid disorder Endocrine diseases including diabetes or impaired glucose tolerance, and gastrointestinal problems
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2015-11-11, 1394/08/20
Ethics committee reference number
IR.ARUMS.REC.1394.255

Health conditions studied

1

Description of health condition studied
Polycystic ovary 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 12 weeks of intervention
Method of measurement
Elisa kit

2

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

3

Description
Testosterone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Secondary outcomes

1

Description
Nitric oxide
Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Follicular-stimulating hormone

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

5

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

6

Description

hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

7

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

8

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Soy isoflavone capsule, 45 mg, daily for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule, daily for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Clinic

Full name of responsible person

Mehri Jamilian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiee

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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, Arak 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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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