

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of the effect of combined probiotic and selenium supplementation compared with the placebo on hormonal profiles, inflammatory factors and oxidative stress biomarkers in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of combined probiotic and selenium supplementation on hormonal profiles, inflammatory factors and oxidative stress biomarkers in patients with polycystic ovary syndrome.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive combined probiotic and selenium supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with polycystic ovary syndrome referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome aged 18 to 40 years. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Intervention group: Combined probiotic, including 2×10⁹ Lactobacillus acidophilus, 2×10⁹ Bifidobacterium bifidum, 2×10⁹ Lactobacillus reuteri, 2×10⁹ Lactobacillus fermentum daily, and selenium supplements (Webber Naturals, Mississauga, Canada), 200 µg, daily, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily for 12 weeks orally.

Main outcome variables

Outcomes: Total testosterone (primary outcome) and biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N22**

Registration date: **2017-12-18, 1396/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-16, 1398/06/25**

Update count: **1**

Registration date

2017-12-18, 1396/09/27

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-04, 1396/09/13

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined probiotic and selenium supplementation compared with the placebo on hormonal profiles, inflammatory factors and oxidative stress biomarkers in women with polycystic ovary syndrome

Public title

Effect of combined probiotic and selenium supplementation in treatment of patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Patients with polycystic ovary syndrome. Individuals aged 18 to 40 years.

Exclusion criteria:

Exclusion criteria: Pregnancy Adrenal hyperplasia Androgen-secreting tumors Hyperprolactinemia Thyroid dysfunction Diabetes

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline, after balanced blocked randomisation, subjects will be allocated into two groups to receive supplement or placebo. 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

Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2017-12-03, 1396/09/12

Ethics committee reference number

IR.ARAKMU.REC.1396.203

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

Total testosterone

Timepoint

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

Method of measurement

Elisa kit

Secondary outcomes

1

Description

SHBG

Timepoint

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

Method of measurement

Elisa kit

2

Description

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

3

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

4

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

7

Description

Beck depression inventory

Timepoint

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

Method of measurement

Questionnaire

8

Description

Depression anxiety and stress scale

Timepoint

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

Method of measurement

Questionnaire

9

Description

General health questionnaire

Timepoint

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

Method of measurement

Questionnaire

10

Description

Modified Ferriman Gallwey

Timepoint

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

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Combined probiotic, including 2×10⁹ Lactobacillus acidophilus, 2×10⁹ Bifidobacterium bifidum, 2×10⁹ Lactobacillus reuteri, 2×10⁹ Lactobacillus fermentum daily, and selenium supplements (Webber Naturals, Mississauga, Canada), 200 µg, daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (Barij Essence, Kashan, Iran), daily for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Clinic

Full name of responsible person

Mehri Jamilian

Street address

Emam Khomeyni Avenue, Arak

City

Arak

Province

Markazi
Postal code
3848176941
Phone
+98 86 3417 3639
Email
mjamilian@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad arjomandzadegan
Street address
Sardasht Avenue, Vice chancellor for research, Arak
University of Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3645
Email
arjomandzadegan@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Kashan
Province
Isfahan
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutritionist
Latest degree
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Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
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Kashan
Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

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