

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Clinical trial of the effect of combined probiotic and selenium supplementation compared with the placebo on metabolic profiles 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 metabolic profiles in patients with polycystic ovary syndrome.

Design

Study design: Randomized double-blind placebo-controlled trial. To decrease potential confounding effects, after balanced blocked randomisation, all participants will be allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Settings and conduct

Among patients with polycystic ovary syndrome referred to Gynecology outpatient Clinic affiliated to Shahid Beheshti 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: Women aged <18 or >40 years, individuals with neoplastic, hepatic, renal or CVD, malabsorptive disorders, current or previous (within the last 6 months) use of antidiabetic, or anti-obesity medications, pregnant women, taking selenium, probiotics and synbiotics supplements within the past 3 months.

Intervention groups

Intervention: Patients will be assigned into two groups to receive combined probiotic and selenium supplements (n=30) or placebo (n=30). Supplements and placebos are similar in shape and size.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082733941N11**

Registration date: **2017-10-02, 1396/07/10**

Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **1**

Registration date

2017-10-02, 1396/07/10

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-07-26, 1396/05/04

Expected recruitment end date

2017-08-02, 1396/05/11

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 metabolic profiles in women with polycystic ovary syndrome

Public title
Effect of combined probiotic and selenium supplementation in treatment of women with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with polycystic ovary syndrome aged 18 to 40 years
Exclusion criteria:
 Women aged <18 or >40 years Individuals with neoplastic, hepatic, renal or CVD, malabsorptive disorders, current or previous (within the last 6 months) Use of antidiabetic, or anti-obesity medications Pregnant women Taking selenium, probiotics and synbiotics supplements within the past 3 months

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To decrease potential confounding effects, after balanced blocked randomisation, all participants will be allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1985711151

Approval date

2017-07-25, 1396/05/03

Ethics committee reference number

IR.SBMU.REC.1396.309

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

Calculation using HOMA formula

Secondary outcomes

1

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

FPG

Timepoint

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

Method of measurement

Enzymatic kit

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 orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Clinic

Full name of responsible person

Azadeh Shabani

Street address

Taleghani hospital, Yaman st, Velenjak, Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway

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zarghi-a@sums.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 of Shahid Beheshti 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

1771844351

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Fax**Email**

asemi_r@yahoo.com

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Ph.D of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Province

Isfahan

Postal code**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