

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of combined probiotic and vitamin D supplementation 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 vitamin D supplementation on metabolic profiles in women 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 vitamin D and probiotic supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with polycystic ovarian syndrome referred to Alavi Clinic affiliated to Ardabil 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 vitamin D supplements (Zahravi, Tabriz, Iran), 50,000 IU vitamin D every 2 weeks, for 12 weeks orally. Control group: Probiotic and vitamin D placebo capsules (Barij essence, Kashan, Iran), probiotic placebo daily and vitamin D placebo every 2 weeks, for 12 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid 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: **IRCT20170513033941N43**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

Registration date

2018-12-29, 1397/10/08

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-03, 1397/09/12

Expected recruitment end date

2019-01-02, 1397/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effects of combined probiotic and vitamin D supplementation on metabolic profiles in women with polycystic ovary syndrome

Public title
Effect of combined probiotic and vitamin D supplementation in the treatment of polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with polycystic ovary syndrome Individuals aged 18 to 40 years.
Exclusion criteria:
Individuals with neoplastic disorders cardiovascular diseases malabsorptive disorders current or previous (within the last 6 months) use of hormonal; antidiabetic and anti-obesity medications.

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m²) and age (<30 and ≥30 y). Then, participants in each block will be randomly 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 the Alavi clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical Sciences

Street address

Daneshgah Avenue

City

Ardabil

Province

Ardabil

Postal code

1771844351

Approval date

2018-12-02, 1397/09/11

Ethics committee reference number

IR.ARUMS.REC.1397.157

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 resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

2

Description

Fasting serum Insulin levels

Timepoint

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

Method of measurement

Elisa kit

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

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 vitamin D supplements (Zahravi, Tabriz, Iran), 50,000 IU vitamin D every 2 weeks, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Probiotic and vitamin D placebo capsules (Barij essence, Kashan, Iran), probiotic placebo daily and vitamin D placebo every 2 weeks, for 12 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alavi Clinic
Full name of responsible person
Dr. Maryamossadat Razavi
Street address
Daneshgah Avenue
City

Ardabil
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1771844351
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+98 31 5546 3378
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razavi.m@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Shahab Bohluli
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s.bohloli@pharmacy.arums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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

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Person responsible for updating data

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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