

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

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

Settings and conduct

Among patients with polycystic ovarian syndrome referred to Naghavi outpatient Clinic, 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: Pregnancy, lactation, adrenal hyperplasia, androgen-secreting tumors, hyperprolactinemia, thyroid dysfunction, diabetes, psychological disorders.

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

General information

Reason for update

correction

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N37**

Registration date: **2018-08-18, 1397/05/27**

Registration timing: **retrospective**

Last update: **2019-10-11, 1398/07/19**

Update count: **2**

Registration date

2018-08-18, 1397/05/27

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

2018-07-02, 1397/04/11

Expected recruitment end date

2018-07-23, 1397/05/01

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 hormonal profiles, inflammatory factors and oxidative stress biomarkers 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:
Inclusion criteria: Patients with polycystic ovary syndrome Individuals aged 18 to 40 years.
Exclusion criteria:
Pregnant women Lactation Adrenal hyperplasia Androgen-secreting tumors Hyperprolactinemia Thyroid dysfunction Diabetes Psychological or psychiatric disorders such as anxiety or depressive symptoms at the enrollment

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 balanced randomisation. Then, 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 the Naghavi outpatient 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 National Institute for Medical Research Development of Iran (NIMAD)

Street address

National Institute for Medical Research Development of Iran, Fatemi Avenue, Tehran

City

Tehran

Province

Isfahan

Postal code

1419693111

Approval date

2018-07-01, 1397/04/10

Ethics committee reference number

IR.NIMAD.REC.1397.205

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
General Health Questionnaire
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

9

Description
DASS
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 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
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Mansoreh Samimi
Street address
Shahid Beheshti Avenue, Kashan
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Kashan
Province
Isfahan
Postal code
8115187159
Phone
+98 31 4446 0180
Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development of Iran (NIMAD)

Full name of responsible person

Dr. Reza Malekzadeh

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National Institute for Medical Research Development of Iran, Fatemi Avenue, Tehran

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malek@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

National Institute for Medical Research Development of Iran (NIMAD)

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**Street address**

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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