Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Isfehan

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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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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1419693111
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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
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Person responsible for updating data

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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