

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on profiles of metabolic in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of probiotic supplementation on hormonal profiles and biomarkers of oxidative stress in patients with polycystic ovary syndrome.

Design

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: Among patients with polycystic ovary syndrome referred to Akbarabadi Clinic affiliated to Iran University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria and aged 18 to 40 years will be included in this study. Exclusion criteria: Smokers, taking probiotic supplements, pregnant women, endocrine diseases including thyroid, diabetes and/or impaired glucose tolerance

Intervention groups

Intervention: Patients will be assigned into two groups to receive probiotic (n=30) or placebo (n=30) per day. Probiotic and placebo capsules are similar in shape and size.

Main outcome variables

Outcomes: Hs-CRP (primary outcome) and nitric oxide (NO), biomarkers of oxidative stress and hormonal profile (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201704235623N112**

Registration date: **2017-04-27, 1396/02/07**

Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**

Update count: **1**

Registration date

2017-04-27, 1396/02/07

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2017-03-30, 1396/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of probiotic supplementation compared with the placebo on profiles of metabolic in women with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with PCOS according to Rotterdam criteria Aged 18 to 40 years Obtaining informed consent

Exclusion criteria:

Smokers Taking probiotic supplements Pregnant women Endocrine diseases including thyroid, diabetes and/or impaired glucose tolerance.

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

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 Iran University of Medical Sciences

Street address

Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-02-27, 1395/12/09

Ethics committee reference number

IR.IUMS.REC.1395.8823215264

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

hs-CRP

Timepoint

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

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

2

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Glutathione

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
Total testosterone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

6

Description
SHBG
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

7

Description
DHEAS
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

8

Description
Hirsutism
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Clinical observation

Intervention groups

1

Description
Intervention group: Probiotic capsule containing three strains of Lactobacillus acidophilus (2×10⁹ CFU/g), Lactobacillus casei (2×10⁹ CFU/g) and Bifidobacterium bifidum (2×10⁹ CFU/g) (Tak Gen Zist, Tehran, Iran),

daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi clinic
Full name of responsible person
Maryam Karamali
Street address
Akbarabadi Hospital, Mowlavi Street, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
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Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran
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Email
dr_moosavi_pul@yahoo.ca
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, Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Maryam Karamali

Position

Gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Position

PhD of Nutrition

Latest degree

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Other areas of specialty/work

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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