

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

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

Protocol summary

Study aim

The aim of this study is to determine the effects of Synbiotic supplementation on metabolic profiles in patients with polycystic ovary syndrome (PCOS).

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 PCOS referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome and aged 18 to 40 years will be included in this study. Exclusion criteria: Smokers, Intake of probiotics, and/or synbiotics supplements within the last 3 months, pregnant women, hyperandrogenism, cushing's syndrome, androgen-secreting tumors, hyperprolactinemia and thyroid dysfunction.

Intervention groups

Intervention: Patients will be assigned to receive Synbiotic supplements or placebo into two groups of intervention (n=30) or control (n=30). Synbiotic supplements and placebos capsules are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and end of the intervention: 3 months.

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: **IRCT201604015623N71**

Registration date: **2016-04-20, 1395/02/01**

Registration timing: **retrospective**

Last update: **2019-10-09, 1398/07/17**

Update count: **1**

Registration date

2016-04-20, 1395/02/01

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2016-03-30, 1395/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Effect of Synbiotic 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

Exclusion criteria:

Smokers Intake of probiotics, and/or synbiotics supplements within the last 3 months Pregnant women Hyperandrogenism Cushing's syndrome Androgen-secreting tumors Hyperprolactinemia Thyroid dysfunction

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

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take synbiotic supplements (n = 30) or placebo (n = 30). 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 Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

IR.Kaums.REC.1394.165

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

Elisa kit

Secondary outcomes**1****Description**

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

2**Description**

HDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

VLDL

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

LDL

Timepoint

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

Method of measurement

Enzymatic kit

6

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: Synbiotic supplements containing three strains of *Lactobacillus acidophilus* (2×10^9 CFU/g), *Lactobacillus casei* (2×10^9 CFU/g) and *Bifidobacterium bifidum* (2×10^9 CFU/g) plus 800 mg inulin, daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule, daily for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

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Shahid Rajaee Avenue, Kashan

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asemi_z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

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Email

research@kaums.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, Kashan 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

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

Nutrition

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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