# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 May 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 eclusion 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)

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+98 36 1534 3570

**Email address**
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**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**
Isfehan
**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 (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 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
**Street address**
Shahid Rajaee Avenue, Kashan
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**Postal code**
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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**
Ghotbe Ravandi Boulevard, Kashan
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**Phone**
+98 31 5554 2999
**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**

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**
Nutrition

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## Person responsible for scientific inquiries

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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