

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical trial of the effect of synbiotic supplementation compared with the placebo on metabolic profiles and biomarkers of oxidative stress in women with polycystic ovary syndrome

#### Protocol summary

##### Study aim

The aim of the current study is to evaluate the effects of synbiotic supplementation on metabolic profiles and biomarkers of oxidative stress in women 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

60 patients with PCOS among women of eligible and referred to Kosar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

##### Participants/Inclusion and exclusion criteria

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

##### Intervention groups

Patients will be assigned to receive either synbiotic supplements (intervention group: n=30) or placebo (control group: n=30).

##### Main outcome variables

Outcomes: Hormonal profiles (primary outcomes) and biomarkers of oxidative stress and hormonal (secondary outcome) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201509115623N53**

Registration date: **2015-09-27, 1394/07/05**

Registration timing: **prospective**

Last update: **2019-09-26, 1398/07/04**

Update count: **2**

##### Registration date

2015-09-27, 1394/07/05

##### 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

Arak University of Medical Sciences

##### Expected recruitment start date

2016-01-01, 1394/10/11

##### Expected recruitment end date

2016-03-15, 1394/12/25

##### 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 and

biomarkers of oxidative stress 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:

Women aged 18-40 years Diagnosed with PCOS

##### Exclusion criteria:

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

#### 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 Arak University of Medical Sciences

###### Street address

Arak University of Medical Sciences

#### City

Arak

#### Province

Markazi

#### Postal code

8715988141

#### Approval date

2015-08-23, 1394/06/01

#### Ethics committee reference number

IR.ARAKMU.REC.1394.160

### 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

Fasting blood sugar

##### Timepoint

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

##### Method of measurement

Enzymatic kit

#### 2

##### Description

Serum dehydroepiandrosterone

##### Timepoint

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

##### Method of measurement

Elisa kit

#### 3

##### Description

Serum total testosterone

##### Timepoint

At the beginning of the study and after 12 weeks of

intervention  
**Method of measurement**  
Elisa kit

#### 4

**Description**  
Plasma malondialdehyde  
**Timepoint**  
At the beginning of the study and after 12 weeks of intervention  
**Method of measurement**  
Spectrophotometry

#### 5

**Description**  
Plasma total antioxidant capacity  
**Timepoint**  
At the beginning of the study and after 12 weeks of intervention  
**Method of measurement**  
Spectrophotometry

#### 6

**Description**  
Plasma glutathione  
**Timepoint**  
At the beginning of the study and after 12 weeks of intervention  
**Method of measurement**  
Spectrophotometry

#### 7

**Description**  
Nitric oxide  
**Timepoint**  
At the beginning of the study and after 12 weeks of intervention  
**Method of measurement**  
Spectrophotometry

#### 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: Synbiotic capsule, Lactobacillus acidophilus (2×10<sup>9</sup> CFU/g), Lactobacillus casei (2×10<sup>9</sup> CFU/g) and Bifidobacterium bifidum (2×10<sup>9</sup> CFU/g) plus 0.8 g 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**  
Kosar Clinic  
**Full name of responsible person**  
Khadijeh Nasri  
**Street address**  
Emam Khomeyni Avenue, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
8715988141  
**Phone**  
+98 86 2769 3000  
**Email**  
khadijeh.nasri2@gmail.com

### **Sponsors / Funding sources**

#### 1

**Sponsor**  
**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Mohammad Rafiee  
**Street address**  
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak  
**City**  
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**Province**  
Markazi  
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**Phone**  
+98 86 3276 9300  
**Email**  
rafiee.mohammad22@gmail.com

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

Isfahan

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**Fax****Email**

asemi\_z@kaums.ac.ir

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

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

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**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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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

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Not

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable