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

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Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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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 (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 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

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Emam Khomeyni Avenue, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiee

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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

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
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Associate professor
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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