Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Study of the Effect of synbiotic supplementation on metabolic status ، serum apelin levels and anthropometric indexes in patients with polycystic ovary syndrome

Protocol summary

Study aim
Determination and comparison of synbiotic supplementation effect on metabolic status, serum apelin levels and anthropometric profiles in patients with polycystic ovary syndrome

Design
Randomized, double-blind, placebo-controlled Population studied: Individuals with polycystic ovarian syndrome were randomly divided into 2 groups, group1 receiving synbiotic (1 capsule 500 mg),group 2 placebo group (1 capsule 500 mg placebo),Supplements will be provided for 8 weeks. Sample size: 68 people (2 groups of 34). Study Intervention: Synbiotic Supplement

Settings and conduct
The aim of this study was to evaluate the effect of synbiotic supplementation on metabolic status in patients with PCOS referring to women's specialized clinic in Tabriz. For each person, the general characteristics questionnaire, anthropometric evaluations,, Food registration and the International Assessment of Physical Activity (IPAQ) will be completed. To measure all biochemical parameters, 10 cc of venous blood is collected fast (at the beginning and end of the study) and their serum will be separated and kept until (70 °) until the tests are performed.

Participants/Inclusion and exclusion criteria
Entry criteria: Women aged 20-45 years and BMI Between 40-25, , PCOS diagnosis based on Rotterdam standard 2003 Exit criteria: history of thyroid disorders, ..., pregnancy and lactation, consumers of anti-obesity drugs ..., sensitivity to synbiotic and probiotic capsules,intake of probiotic , perebiotic, synbiotic in the last three months And during the study, regular consumption of probiotic products

Intervention groups
group1 receiving synbiotic (1 capsule 500 mg) group 2 placebo group (1 capsule 500 mg placebo)

Main outcome variables
The effect of synbiotic supplementation on metabolic status, serum apelin levels and anthropometric profiles

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100408003664N19**
Registration date: **2018-03-18, 1396/12/27**
Registration timing: **prospective**

Last update: **2018-03-18, 1396/12/27**
Update count: **0**

Registration date
2018-03-18, 1396/12/27

Registrant information

Name
Maryam Rafraf

Name of organization / entity
Tabriz University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effect of synbiotic supplementation on metabolic status ، serum apelin levels and anthropometric indexes in patients with polycystic ovary syndrome

Public title

Effect of synbiotic supplementation in patients with polycystic ovary syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

• Women with PCOS aged 20-40 years • Diagnosis of PCOS in patients by Gynecologist and according to Rotterdam Standard 2003• The BMI range is between 40-25 m ^ 2/ kg

Exclusion criteria:

• History of thyroid disorders, hyperprolactinemia, Cushing's syndrome, liver and kidney disease, cardiovascular disease, digestive diseases (food allergies, celiac disease, irritable bowel disease), high blood pressure and diabetes. Diagnosis of non-disease By asking the patient, using the existing tests and under the supervision of the doctor will be done. • Pregnancy and breastfeeding • Consumers of anti-obesity drugs and blood lipid lowering drugs, anticoagulants and glucocorticoids • Using a weight loss diet • smoking • Athlete or regular exercise • Sensitivity to synbiotic and probiotic capsules • Antibiotic use a month ago • Use of any dietary supplements in the last 2 months or during the study • Receiving probiotics, perebiotic, synbiotics during the last three months and during the study • Regular consumption of probiotic products

Age

From **20 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups.A random sequence is generated using the STATA14 software.During the random assignment, individuals in the groups will be classified according to age and BMI variables

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind practices: Trials that are planned in a way that neither the studied subjects nor the observers (researchers) know who the group is.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Science

Street address

Tabriz University of Medical Science,Nutrition Faculty,Attar Neyshabori,Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-02-24, 1396/12/05

Ethics committee reference number

IR.TBZMED.REC.1396.1080

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

Fasting blood sugar

Timepoint

Begining and end of the intervention

Method of measurement

Analysing With Spectrophotometer

2

Description

Level of Serum Insulin

Timepoint

Begining and end of the intervention

Method of measurement

Analysing with ELISA

3

Description

HOMA-IR

Timepoint

Begining and end of the intervention

Method of measurement

Calculated According to The Formula

4

Description

Total Cholestrol

Timepoint

Begining and end of the intervention

Method of measurement

Analysing With Spectrophotometer

5

Description

HDL-C

Timepoint

Begining and end of the intervention

Method of measurement

Analysing With Spectrophotometer

6

Description

LDL-C

Timepoint

Begining and end of the intervention

Method of measurement

Calculated According to The Friedewald Formula

7

Description

TG

Timepoint

Begining and end of the intervention

Method of measurement

Analysing With Spectrophotometer

Secondary outcomes

1

Description

Apelin

Timepoint

Beginning and end of intervention

Method of measurement

Analysing With ELISA

2

Description

anthropometric indexes

Timepoint

Beginning and end of intervention

Method of measurement

Measuring with scales and meters

Intervention groups

1

Description

Intervention group: En Interventions 1: 500mg capsules of synbiotic 1 per day for 8 weeks Interventions ,, Half an hour after lunch, the product of Biostimiran Company

Category

Treatment - Drugs

2

Description

Control group: Placebo: 500 mg capsule 1 per day for 8 weeks, half an hour after lunch

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra hospital

Full name of responsible person

Sima Darvishi

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South Army Streets, Garden of the Nineh Cross

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Sima Darvishi

Position
Master's Degree in Nutrition Sciences

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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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