Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of synbiotic on insulin resistance, gut microbiota, sex hormones and morphology of ovaries' cysts in women with poly cystic ovarian syndrome

Protocol summary

Summary

Polycystic ovarian syndrome includes a series of metabolic disorders including insulin resistance and sexual hormonal disorders. Some studies point to the fact that imbalance in intestinal bacteria increases the immune response followed by inflammation and then disrupts insulin receptors and occur insulin resistance. this leading insulin resistance, increased androgens, and follicular growth. So, supplementation with synbiotics seems to help the healthy environment of the intestine. In this study, 80 women aged 18 to 45 years old, according to the inclusion criteria, were randomly divided into two groups receiving daily synbiotic capsules for 8 weeks and the placebo group. The study was three-blind and the study variables included fasting glucose, fasting insulin, HOMA-I, IGF-1, AMH, LH, FSH, intestinal flora changes, and ultrasonography of ovarian cysts at the beginning and the end of the study In both groups, measurements are measured and then compared with each other. Also, the 24-hour food recall and physical activity questionnaire is measured at first, 4th and 8th week,to evaluate feed intake.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050233767N1**
Registration date: **2017-09-22, 1396/06/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

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Name of organization / entity

Qazvin University of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Qazvin university of medical sciences

Expected recruitment start date

2017-08-22, 1396/05/31

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic on insulin resistance, gut microbiota, sex hormones and morphology of ovaries' cysts in women with poly cystic ovarian syndrome

Public title

the effect of synbiotic supplementation on poly cystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: The willingness to collaborate in the plan, being between the ages of 18 and 45, has at least

two criteria of Rotterdam's three criteria for detecting the syndrome and having a BMI of between 25 and 35 kg / m². exclusion criteria: Unwillingness to continue to participate in the study, inadequate supplementation (less than 80% of supplements), and the achievement of any non-inclusion criteria including pregnancy, lactation, menopause, drug use during the past three months include contraceptives, glucocorticoid, Lipid-lowering drugs, Weight loss drugs, Ovulation induction drugs, Estrogenic or anti-androgenic drugs, Underlying illnesses, Infectious diseases, Inflammatory disease, Adrenal gland abnormal, Cushing's syndrome, Adrenal gland tumor, Low Hyperthyroidism, Prolactinemia, Acromegaly, Diabetes and Cancer, Hormone Therapy over 3 months Past and use of probiotic, prebiotic and synbiotic supplements over the past 3 months

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
qazvin university of medical sciences

Street address
Shahid Bahonar blv, qazvin university of medical sciences

City
qazvin

Postal code
3419759811

Approval date
2017-02-27, 1395/12/09

Ethics committee reference number
IR.QUMS.REC.1395.295

Health conditions studied

1

Description of health condition studied
poly cystic ovarian syndrome

ICD-10 code
E28.2

ICD-10 code description
ovarian dysfunction

Primary outcomes

1

Description
sex hormones

Timepoint
at first/ end of study

Method of measurement
elisa

Secondary outcomes

1

Description
serum insulin

Timepoint
at first/ end of study

Method of measurement
elisa

Intervention groups

1

Description
intervention group: 1 capsule (500 mg of synbiotic supplementation)/ daily/ 2 months

Category
Treatment - Drugs

2

Description
control group: 1 placebo supplementation/ daily/ 2 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
kosar medical center

Full name of responsible person
Hamideh Pakniyat

Street address

City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
research deputy , Qazvin university of medical sciences
Full name of responsible person
Maryam Javadi
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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
research deputy , Qazvin university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty