

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

maryam aghayan

Name of organization / entity

Qazvin University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2631 8035

Email address

maryam.aghayan9@gmail.com

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

Street address

Shahid Bahonar Blv, Qazvin university of medical sciences

City

Qazvin

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

Contact

Name of organization / entity

Health school, Qazvin university of medical sciences

Full name of responsible person

Maryam Aghayan

Position

master of science in nutrition

Other areas of specialty/work

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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