Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of probiotic supplements on clinical, endocrine and immunological parameters in woman with polycystic ovarian syndrome (PCOS)

Protocol summary

Summary

The aims of study is to investigate the effects of probiotic supplement on clinical, endocrine, and immunological profile in women with poly cystic ovary syndrome Study design: Randomized, double-blind, placebo- controlled trial, single-center Inclusion criteria: age between 18 to 45 years ild; not using any kind of medication or supplements except Cyproterone acetate compound; no history of any chronic disease (diabetes, thyroid disease, autoimmune, cancer,..) during trial; not being professional athlete; no desire for following up an infertility treatment for the next months. Exclusion criteria: smoking; pregnancy; lactation; tend to pregnancy for next three months; getting common cold or flu more than 5 days during trial; no desire for cooperation; making the major change in diet or physical activity during trial; using any immune-oppressive medication. Sample size: 60. Intervention: probiotic supplement (lactoBacillus 1000000000 CFU) 2 times per day, and maltodextrin capsule as a placebo. Duration of intervention: 3 months. Study outcomes: measuring hormones profile (LH, FSH, DHEA, and Testestrone), serum glucose, insulin, IL-6, IL-10, hs_CRP, dominant follicle, ovary size in the middle of cycle Second outcomes: Lipid profile, weight, BMI, waist circumstance, HOMA-IR, The number of days of the menstrual cycle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081429362N1**
Registration date: **2016-09-08, 1395/06/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-08, 1395/06/18

Registrant information

Name
Nila Ghanei

Name of organization / entity
National nutrition and food technology institute, school of nutrition and food sciences, Shahid Behe

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Institute of Iran, Shahid Beheshty University of Medical Science

Expected recruitment start date
2016-07-09, 1395/04/19

Expected recruitment end date
2016-09-09, 1395/06/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effects of probiotic supplements on clinical, endocrine and immunological parameters in woman with polycystic ovarian syndrome (PCOS)

Public title

The effects of Lacatobacillus on poly cystic onarian syndrom (PCOS)

Purpose

Treatment

Inclusion/Exclusion criteria

Target population sample of women with poly cystic ovary syndrome in women with poly cystic ovary syndrome referred to Ebne Sina hospital, Tehran, Iran. Inclusion criteria: age between 18 to 45 years ild; not using any kind of medication or supplements except Cyproterone acetate compound; no history of any chronic disease (diabetes, thyroid disease, autoimmune, cancer,..) during trial; not being professional athlete; no desire for following up an infertility treatment for the next months. Exclusion criteria: smoking; pregnancy; lactation; tend to pregnancy for next three months; getting common cold or flu more than 5 days during trial; no desire for cooperation; making the major change in diet or physical activity during trial; using any immune-oppressive medication.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nutrition Sciences and Food Technology , Shahid Beheshti University of Medical SciencesSci

Street address

West Arghavan St, Farahzadi Blv, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-06-25, 1395/04/05

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1395.54

Health conditions studied

1

Description of health condition studied

poly cystic ovary syndrome (PCOS)

ICD-10 code

IV

ICD-10 code description

E28.2

Primary outcomes

1

Description

hs-CRP

Timepoint

beginning of trial/ end of trial (3 months later)

Method of measurement

Eliza

2

Description

IL-6

Timepoint

beginning of trial/ end of trial (3 months later)

Method of measurement

Eliza

3

Description

IL-10

Timepoint

beginning of trial/ end of trial (3 months later)

Method of measurement

Eliza

4

Description

LH

Timepoint

beginning of trial/ end of trial (3 months later)

Method of measurement

Eliza

5

Description

FSH

Timepoint

beginning of trial/ end of trial (3 months later)

Method of measurement

Eliza

6

Description

DHEA

Timepoint

beginning of trial/ end of trial (3 months later)
Method of measurement
Eliza

7

Description
TESTOSTERONE
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
Eliza

8

Description
serum insulin
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
Eliza

9

Description
serum glucose
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
enzymatic method

10

Description
dominant follicle
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
ultrasound (sonography)

11

Description
ovary size
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
ultrasound (sonography)

Secondary outcomes

1

Description
TG
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
enzymatic

2

Description
weight
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
weight scale

3

Description
LDL
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
enzymatic

4

Description
waist circumstance
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
meter

5

Description
BMI
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
weight(kg)/height2(m2) (Metric Units)

6

Description
HOMA-IR
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
{[fasting insulin (μU/ml)] × [fasting glucose (mmol/l)]}/22.5

7

Description
The number of days of the menstrual cycle
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
questioner

8

Description
HDL
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
enzymatic

9

Description
total cholesterol
Timepoint
beginning of trial/ end of trial (3 months later)
Method of measurement
enzymatic

Intervention groups

1

Description
probiotic Lactobacillus/109 CFU/ 2 times per day/ for 3 months/ keep in the refrigerator/ Lactobacillus acidophilus Lactobacillus plantarum Lactobacillus fermentum Lactobacillus gasseri Fructooligosaccharides
Category
Treatment - Drugs

2

Description
placebo: maltodextrin/ made by same company with exact shape, size, color/ 2 times per day/ for 3 months/ keep in the refrigerator
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebne Sina clinic
Full name of responsible person
Dr Ali Amiri (OB,GYN)
Street address
5th floor, Ebne Sina Clinic, Sadeghieh second SQ, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Nutrition and Food Sciences Institute Iran, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Esmat Naseri
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National Nutrition and Food Sciences Institute, West Arghavan, Farahzadi Blvd.Teh, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Nutrition and Food Sciences Institute Iran, Shahid Beheshti 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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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