

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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 old; 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 Testosterone), 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 circumference, 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 Beheshti

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2236 0656

###### Email address

nilaghanei@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

National Nutrition and Food Technology Institute of Iran,  
Shahid Beheshti 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 Lactobacillus on poly cystic ovarian syndrome (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 old; 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 circumference

**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

#### Street address

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

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Nila Ghanei

#### Position

PhD student of nutrition

#### Other areas of specialty/work

#### Street address

National Nutrition and Food Technology Institute of IRAN. Shahid Beheshti University of Medical Sciences, West Arghavan, Farahzadi Blvd.

#### City

Tehran

#### Postal code

#### Phone

+98 21 2236 0656

#### Fax

#### Email

nilaghanei@sbmu.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Dr. Esmat Naseri

#### Position

PhD in Nutrition Sciences

#### Other areas of specialty/work

#### Street address

National Nutrition and Food Technology Institute of IRAN. Shahid Beheshti University of Medical Sciences, West Arghavan, Farahzadi Blvd.

#### City

Tehran

#### Postal code

#### Phone

+98 21 2236 0656

**Fax**  
**Email** nasser\_i\_esm@hotmail.com; esm\_nasser\_i@sbmu.ac.ir  
**Web page address**

+98 21 2236 0656  
**Fax**  
**Email** nillagh@yahoo.com; nilaghane\_i@sbmu.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Nila Ghanei  
**Position**  
PhD student  
**Other areas of specialty/work**  
**Street address**  
National Nutrition and Food Technology Institute of  
IRAN. Shahid Beheshti University of Medical Sciences,  
West Arghavan, Farahzadi Blvd.  
**City**  
Tehran  
**Postal code**  
**Phone**

## 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*