

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Surrvey the effect of Probiotic Supplement on antropometric indexes, hormonal and metabolic parameters, clinical symptoms and serum apelin level in women with polycystic ovary syndrom -----

Protocol summary

Summary

Objectives: Determine the effect of probiotic supplementation on antropometric indexes, hormonal and metabolic parameters, clinical symptoms and serum apelin level in women with polycystic ovary syndrom syndrome. Design , Setting and Conduct: 88 samples of obese and overweight women with polycystic ovarian syndrome in the 37-19 year age range will be divided into two groups. The study randomized, double-blind clinical trial will be conducted in two phases. At the first variables measured and after probiotic supplement and placebo will be available to participants. After 12 weeks at the end of intervening variables will be re-evaluated. Participant (including major eligibility criteria): Inclusion criteria; Obese and overweight women ($BMI \leq 25$); in the age range 37-19 years, with polycystic ovary syndrome Non-inclusion criteria; history of systemic and chronic diseases; smoking; The use of some medications, supplements and diets less than two months from the start of the study Exclusion criteria; pregnancy and infertility complaints during the study Intervention: The control group will receive placebo and the intervention group will receive probiotic supplement Lactocare (Zist Takhmir company) in the form of capsules containing 500 mg orally, twice daily for 12 weeks. Main outcome measures(primary and secondary outcome variables): Body mass index, insulin resistance , insulin sensitivity and serum apelin level and secondary level, lipid profiles, sex hormone levels and changes in their symptoms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110515536N2**

Registration date: **2015-12-19, 1394/09/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-19, 1394/09/28

Registrant information

Name

Mohammad Javad Hosseinzadeh

Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

Country

Iran (Islamic Republic of)

Phone

+98 21 8899 3059

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-09-25, 1394/07/03

Expected recruitment end date

2016-04-22, 1395/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Surrvey the effect of Probiotic Supplement on antropometric indexes, hormonal and metabolic

parameters, clinical symptoms and serum apelin level in women with polycystic ovary syndrom -----

IRTUMS.REC.1394.809

Public title

Surrvey The effect of probiotic supplementation on weight changes, hormonal and metabolic levels in women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women 37-19 years old; Obese and overweight ($BMI \leq 25$); Diagnosis of polycystic ovary syndrome (PCOS diagnosis based on the Rotterdam criteria 2003) Non-inclusion criteria: history of systemic and chronic diseases; smoking; The use of some medications, supplements and diets less than two months from the start of the study Exclusion criteria: pregnancy; During the study complained of infertility

Age

From **19 years** old to **37 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

How randomized using of closed envelopes method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of Medical Sciences

Street address

Ghods st. keshavarz blv

City

Tehran

Postal code

Approval date

2015-09-21, 1394/06/30

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Poly cystic ovary syndrom

ICD-10 code

Endocrine,

ICD-10 code description

E28.2

Primary outcomes

1

Description

Body mass index

Timepoint

Before and 3 month after the intervention

Method of measurement

Calculated by the formula

2

Description

Insulin resistance and insulin sensitivity

Timepoint

Before and 3 month after the intervention

Method of measurement

Calculated by the formula

3

Description

Plasma apelin level

Timepoint

Before and 3 month after the intervention

Method of measurement

Laboratory method

Secondary outcomes

1

Description

lipid profiles level

Timepoint

Before and 3 month after the intervention

Method of measurement

Laboratory method

2

Description

Sex hormones level

Timepoint

Before and 3 month after the intervention

Method of measurement

Laboratory method

3

Description

Changing clinical symptoms

Timepoint

Before and 3 month after the intervention

Method of measurement

Through questionnaires and clinical examination

Intervention groups

1

Description

control group:plasebo,capsule 500mg,2times/day,for12 week

Category

Treatment - Drugs

2

Description

Intervention group:Lactocare probiotic supplement(Zist takhmir company), oral Capsule 500mg,2times/day,for 12 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women,s comprehensive hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Elham Karimi

Street address

Hojjatdost st, Naderi st, Keshavarz blv/School of Nutritional Sciences and Dietetics

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Investigator

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

Tehran university of Medical Sciences/School of Nutritional Sciences and Dietetics

Full name of responsible person

Elham Karimi

Position

MS Student of Nutritional Sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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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