Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Oct 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 ctriteria): Inclusion criteria;Obese and overweight women (BMI≤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)

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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 ----------

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≤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
IRTUMS.REC.1394.809

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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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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