Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparision of the effect of vitamin D3 and probiotic containing lactic acid bacteria co-supplementation with vitamin D3 on serum 25(OH)D levels in patients with polycystic ovary syndrome.

Protocol summary

Study aim
Determining the simultaneous effect of vitamin D supplementation and probiotics containing lactic acid bacteria compared to vitamin D supplementation on serum 25(OH) D levels in patients with polycystic ovary syndrome

Design
A randomized, parallel-group clinical trial, phase 3, on 94 patients. People were equally divided into two groups based on the table of random numbers. The first group of this study is the probiotic-vitamin D group, and the second group is the vitamin D group. This study was not blinded.

Settings and conduct
Study setting: Imam Khomeini Medical Education Center in Urmia. P. Probiotic supplement in the form of lactofem capsules will be provided from Zist takhmir Company, and vitamin D3 supplement will be provided in the form of vitamin D3 gelatin capsules with a dose of 50,000 from Dana Pharmaceutical Company. The intervention period in this trial is 12 weeks. A blood sample of 2 ml will be taken from the participants in the study at the beginning and at the end of the study on a specific day by a laboratory science expert of the center, and the serum level of 25 hydroxyvitamin D will be measured by ELISA method. will be taken. People are asked to visit the nutrition clinic every two weeks and receive their next supplement package.

Participants/Inclusion and exclusion criteria
Patients with polycystic ovary syndrome who have referred to Imam Khomeini Medical Education Center to diagnose their disease.

Intervention groups
The probiotic-vitamin D group will receive 50,000 IU of vitamin D3 every two weeks along with one Lactofem capsule daily. In the vitamin D group, they will receive 50,000 IU of vitamin D3 every 2 weeks.

Main outcome variables
Serum level of 25(OH)D

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221121056563N1**
Registration date: **2023-01-04, 1401/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-04, 1401/10/14**
Update count: **0**

Registration date
2023-01-04, 1401/10/14

Registrant information
Name
Shaghayegh Torabali
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-12-02, 1401/09/11
Expected recruitment end date
2023-07-22, 1402/04/31
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the effect of vitamin D3 and probiotic containing lactic acid bacteria co-supplementation with vitamin D3 on serum 25(OH)D levels in patients with polycystic ovary syndrome.

Public title

Comparision of the effect of vitamin D3 and probiotic containing lactic acid bacteria co-supplementation with vitamin D3 on serum 25(OH)D levels in patients with polycystic ovary syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18-40 years A resident of Urmia Diagnosis of PCOS based on the Rotterdam indices. The Rotterdam criteria include having more than two of these symptoms: oligo/no ovulation, hyperandrogenism (symptoms such as hirsutism, acne, male pattern alopecia, increased free testosterone) and polycystic ovaries based on ultrasound (having 12 or more The follicle in each ovary is 2-9 mm in size People with blood levels of 25 hydroxyvitamin D less than 30 ng/ml

Exclusion criteria:

Pregnancy or lactation, Endocrine glands problems: adrenal hyperplasia, androgen-secreting tumor, hyperprolactinemia, thyroid dysfunction, diabetes, Cushing's syndrome. History of premature menopause, smoking or history of smoking, significant changes in diet, and people who have taken antibiotics one month before the start of the study. Taking a probiotic supplement. Having any disorder other than PCOS that is associated with excessive androgens and menstrual irregularities, vitamin D sensitivity Having a chronic disease such as autoimmune disease, active liver disease, having a history of heart and kidney diseases, pancreatitis, lung disease and having a diet and any type of additional physical activity such as aerobics and using omega-3 and multivitamins Using drugs that interfere with vitamin D, such as anticonvulsants, rifampin and isoniazid, digoxin, and magnesium hydroxide and aluminum hydroxide antacids. alcohol consumption Allergy to probiotics

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in the form of a table of random numbers. A table of random numbers is a collection of numbers that are generated completely randomly without a specific pattern or order and are made into a table. In order to use the table of random numbers, first the direction of reading the numbers in the table is predetermined (for example, up, down, left or right), the second assumption is to consider numbers for different groups (for example, even numbers for vitamin D group) and odd numbers for the probiotic-vitamin D group). In fact, the patients referred to the endocrinology clinic of Imam Khomeini (RA) Urmia Medical Education Center are selected by the endocrinology subspecialist based on the entry and exit criteria. Each selected patient goes to the researcher, then the researcher puts his hand on one of the numbers and moves in one of the predetermined directions and records the number. If the number is even, the patient is placed in the vitamin D group, and if the patient's odd number was placed in the probiotic-vitamin D group. Patients enter the study in order and receive the code related to the desired group according to the method explained.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Boostan dormitory، Zaker St، Apadana crossroad، Urmia city، West Azarbaijan

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2022-10-29, 1401/08/07

Ethics committee reference number

IR.UMSU.REC.1401.291

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

2

Description of health condition studied
Vitamin D deficiency, unspecified
ICD-10 code
E55.9
ICD-10 code description
Vitamin D deficiency, unspecified

Primary outcomes

1

Description
Serum level of 25 hydroxyvitamin D
Timepoint
The beginning and end of the study
Method of measurement
blood sample

Secondary outcomes

1

Description
Weight
Timepoint
The beginning and end of the study
Method of measurement
Scale

2

Description
body composition
Timepoint
The beginning and end of the study
Method of measurement
Bioelectrical Impedance Analysis

3

Description
Body Mass Index
Timepoint
The beginning and end of the study
Method of measurement
Bioelectrical Impedance Analysis

Intervention groups

1

Description
Intervention group1: Probiotic group - Vitamin D 50,000 IU vitamin D3 every two weeks along with one capsule of Lactofem containing Lactobacillus rhamnosus, Lactobacillus fermentum, Lactobacillus casei, Lactobacillus plantarum, Lactobacillus acidophilus, Lactobacillus gasseri and Lactobacillus bulgaricus in the amount of 109 CFU along with fructo-oligosaccharides as prebiotics. They will receive the prebiotic daily.
Category
Treatment - Other

2

Description
Intervention group 2:In the vitamin D group, they will receive 50,000 IU of vitamin D3 every 2 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Medical Education Center
Full name of responsible person
Rasoul Zarrin
Street address
Imam Khomeini University Imam Khomein Hospital-Ershad Ave-Modarres Blvd-Urmia-Iran
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Urmia
Province
West Azarbaijan
Postal code
5715781351
Phone
+98 44 3346 9933
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13141375a@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Rasoul Zarrin
Street address
Urmia University of Medical Sciences، Ourjans room، Resalat Blvd، Urmia city، Azarbaijan provience
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Grant name

Grant code / Reference number

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

Title of funding source
Oroumia University of Medical Sciences

Proportion provided by this source
30

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Shaghayegh Torabali

Position
Collegian

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Boostan dormitory، Zaker St، Apadana Crossroad، Urmia city، West Azarbaijan provience

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Name of organization / entity
Oroumia University of Medical Sciences

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available