Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Investigating the Effects of Single Dose and Co-Supplementation of Vitamin D and Omega-3 on Anthropometric Factors, Lipid and Glycemic Profile, and the Status of Sex Hormone Binding Globulin in Women with Polycystic Ovary Syndrome

Protocol summary

Study aim
The comparison of the effects of vitamin D-omega-3 fatty acids co-supplementation with vitamin D and omega-3 fatty acids alone on anthropometric, metabolic stress, hypertension and and serum androgen profile in women with poly cystic ovary syndrome

Design
This study was a randomized double-blind placebo-controlled Parallel 4 group of eight weeks clinical trial

Settings and conduct
At the beginning of the present study,all patients were asked to carry out their capsules in second (end of week 4) and third (end of Eighth week) to ensure full consumption . Follow patients to control them in terms of taking capsules, the possibility of severe side effects or symptoms of poisoning with supplements used and to prevent the loss of samples, each week to telephone and also through referring patients to Shahid Motahari Clinic in Shiraz at the end of the fourth and eighth weeks

Participants/Inclusion and exclusion criteria
Inclusion criteria This syndrome is defined by the Rotterdam Diagnostic Criteria by Gynecologist Excluding any drug or surgical treatment to treat clinical symptoms associated with polycystic ovary syndrome except ocp ; No history of any allergy, intolerance or harmful drug reaction to the studied supplements, Age range ..18-45 ; Ability to understand study objectives and provide written informed consent Being within the BMI range of 18.5-45 ; Residence in Shiraz and willingness to participate in the study Exclusion criteria The incidence of severe side effects or symptoms of poisoning with supplements used during the study period;Initiate intake or any changes in the type or dosage;Getting pregnant during the study period;Non-adherence to the study protocol

Intervention groups
The four groups of each group are 20 (a) vitamin D and omega-3, B) vitamin D and pelacebo omega-, 3 C) Omega-3 and pelacebo vitaminD, d)pelacebo

Main outcome variables
metabolic indicators

General information

Reason for update
With regards, the only changes that the research team requests to update the information and match it with the extracted article are the addition of the height factor and the correction of the study completion date. The rest of the information has already been confirmed.

Acronym

IRCT registration information
IRCT registration number: **IRCT20100223003408N7**
Registration date: **2020-02-23, 1398/12/04**
Registration timing: **retrospective**

Last update: **2022-09-19, 1401/06/28**
Update count: **2**

Registration date
2020-02-23, 1398/12/04

Registrant information

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Name of organization / entity
Shiraz University of Medical Sciences, Nutrition Department

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-04-05, 1396/01/16
Expected recruitment end date
2017-09-11, 1396/06/20
Actual recruitment start date
2017-04-30, 1396/02/10
Actual recruitment end date
2017-10-17, 1396/07/25
Trial completion date
2017-12-21, 1396/09/30

Scientific title
Investigating the Effects of Single Dose and Co-Supplementation of Vitamin D and Omega-3 on Anthropometric Factors, Lipid and Glycemic Profile, and the Status of Sex Hormone Binding Globulin in Women with Polycystic Ovary Syndrome

Public title
Investigating the Effects of Single Dose and Co-Supplementation of Vitamin D and Omega-3 in women with poly cystic ovary syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
This syndrome is defined by the Rotterdam Diagnostic Criteria by Gynecologist Excluding any drug or surgical treatment to treat clinical symptoms associated with polycystic ovary syndrome except ocp No history of any allergy, intolerance or harmful drug reaction to the studied supplements Age range ..18-45 Being within the BMI range of 18.5-40 Ability to understand study objectives and provide written informed consent Residence in Shiraz and willingness to participate in the study
Exclusion criteria:
Suffering from hormonal disorders including Edison's disease, Cushing's disease, hyperparathyroidism, hypo- or hyperthyroidism Having history of chronic diseases including cancer, heart disease, diabetes, stroke, fibromyalgia, kidney, or liver defects Having history of food and drug allergies Starting drug or surgical therapy for clinical symptoms associated with PCOS except oral contraceptive pills (OCPs) Smoking or any drug addiction Pregnancy and lactation Being on a special diet in the last year Using any dietary supplement, Having oral or injectable nutritional supplements containing vitamin D in the last 3 months Consuming nutritional supplements containing fish oil or Omega-3 fatty acids in the last 3 months Having fish in the diet more than 3 servings per week during last 3 months History of severe side effects or symptoms of poisoning with the current study supplements Lack of adherence to the study protocol
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **107**
More than 1 sample in each individual
Number of samples in each individual: **2**
The beginning and the end of the study
Actual sample size reached: **80**
More than 1 sample in each individual
Actual sample size in each individual: **2**
The beginning and the end of the study
Randomization (investigator's opinion)
Randomized
Randomization description
samples were categorized using a Permuted block randomization method (29) based on whether or not using OCP by using Random Allocation Software as 1: 1: 1: 1 and equally to one of the 4 groups
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinded groups in the study include participants and researchers. After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups. The doctor is given a table of coded numbers in advance, and the patients are entered into the study in the order of the numbers in the table. Therefore, the present study is double-blind. Vitamin D, Omega-3 and placebo capsules have the same shape, color, and size and are delivered to the patient in the package.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
shiraz university of medical science
Street address
zand street
City
shiraz
Province
Fars
Postal code
7134814336
Approval date

2018-01-31, 1396/11/11

Ethics committee reference number

IR.SUMS.REC.1396.103

Health conditions studied

1

Description of health condition studied

polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

polycystic ovary syndrome

Primary outcomes

1

Description

TG

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

Autoanalyzer

2

Description

TC:total cholesterol

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

Autoanalyzer

3

Description

HDL-C:high-density lipoprotein cholesterol

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

Autoanalyzer

4

Description

LDL-C:Low-density lipoprotein cholesterol

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

Autoanalyzer

Secondary outcomes

1

Description

sex hormone binding globulin :SHBG

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

ELISA

2

Description

FBS: fasting blood sugar

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

Autoanalyzer

3

Description

Physical Activity

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

questionnaire

4

Description

Weight

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

Low-weight, no-shoe weight using Digital Balance Digital Balance

5

Description

BMI:body mass index

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

Formula

6

Description

WC: Waist circumference

Timepoint

Beginning and end of the study (first week and eighth week)

Method of measurement

Meter

7

Description

Homeostasis model assessment insulin resistance (HOMA-IR)

Timepoint
Beginning and end of the study (first week and eighth week)
Method of measurement
Formula

8

Description
serum Insulin
Timepoint
Beginning and end of the study (first week and eighth week)
Method of measurement
ELISA

9

Description
Height
Timepoint
Beginning and end of the study (first week and eighth week)
Method of measurement
With minimum coverage and no shoes, using wall meter

Intervention groups

1

Description
Vitamin D group: received one vitamin D capsule (Zahravi Pharmaceutical Company, Tehran, Iran) (50000 IU/weekly) + two placebo capsules (paraffin oil; daily).
Category
Treatment - Other

2

Description
Omega-3 (O3) group: received two O3 capsules (Zahravi Pharmaceutical Company, Tehran, Iran) daily (each one contained 360 mg eicosapentaenoic acid (EPA) and 240 mg docosahexaenoic acid (DHA)) + one placebo capsule (paraffin oil; weekly).
Category
Treatment - Other

3

Description
Vitamin D + O3 group: received one vitamin D capsule (50000 IU/weekly) + two O3 capsules daily (each one contained 360 mg EPA and 240 mg DHA).
Category
Treatment - Other

4

Description
Placebo group: received one placebo capsule (paraffin oil; weekly) + two placebo capsule (paraffin oil; daily).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Clinic in Shiraz
Full name of responsible person
Dr. Nasrin Asadi
Street address
Namazi Square Clinic of Shahid Motahari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
Shiraz University of Medical Sciences
Proportion provided by this source
100
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

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Maryam Ekramzade

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Latest degree

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Other areas of specialty/work

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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