

# 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 placebo omega-, 3 C) Omega-3 and placebo vitaminD, d) placebo

##### 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

##### Name

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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

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Namazi Square Clinic of Shahid Motahari

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**Province**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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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

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## Person responsible for general inquiries

### Contact

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Shiraz University of Medical Sciences  
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## Person responsible for updating data

### Contact

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## Person responsible for scientific inquiries

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**Province**  
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**Postal code**  
7153675541  
**Phone**

## 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