

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of effectiveness of Omega3 supplementation on poly cystic ovary syndrome(PCOs) symptoms and metabolic syndrome according of the NIH criteria

Protocol summary

Summary

This study aimed to determine the effectiveness of omega-3 on improving the symptoms of PCOS and the metabolic syndrome in patients with poly cystic ovarian syndrome. This study is a double blind prospective randomized clinical trial. The study population included women with polycystic ovary syndrome will refer to two hospitals in Isfahan. Inclusion criteria: PCOS disease, according to the NIH3. Exclusion criteria: any endocrine disease. patient will take drug or placebo upon on closed pocket method. Intervention group will take omega 3 supplements with dose of 2 gr per day for six months (two capsules), but control group will receive 2 placebo capsules daily for six month. Finally, lab findings and the recovery rate of menstrual disorders and hirsutism in both groups will compare. Sample size is 44 patient in each groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604193924N3**

Registration date: **2017-03-10, 1395/12/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-10, 1395/12/20

Registrant information

Name

Behnaz Khani

Name of organization / entity

Isfahan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 913 314 6418

Email address

khani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of Omega3 supplementation on poly cystic ovary syndrome(PCOs) symptoms and metabolic syndrome according of the NIH criteria

Public title

Clinical trial of comparison of effectiveness of Omega-3 supplement on PCOS and metabolic syndrome with placebo

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Patients who have informed consent ; PCOS disease, according to the NIH3 ; age between 18-40 ; Exclusion criteria: smoking, use of oral pregnancy pill or alcohol or fish oil in 3 month ago or into the study ; pregnancy; have disease of kidney or liver or heart or

thyroid ; diabetes ; hyperprolactinemia ; Cushing, Adrenal congenital hyperplasia, menopause ; the patient withdrew into the study ; Failure to follow the next visit

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: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

patient will take closed pocket and drug store dependent on number (single or pair) will give drug or placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan university of medical sciences

Street address

isfahan, Hezar jerib avenue, Isfahan university of medical sciences

City

Isfahan

Postal code

81746-73461

Approval date

2015-01-28, 1393/11/08

Ethics committee reference number

394057

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

2

Description of health condition studied

menstrual disorder

ICD-10 code

n92.6 , n9

ICD-10 code description

hypomenorrhea Nos, bleeding NOs, periods NOS

3

Description of health condition studied

metabolic syndrom

ICD-10 code

E88.9

ICD-10 code description

metabolic disorder unspecified

4

Description of health condition studied

hyperandrogenism

ICD-10 code

E28.1

ICD-10 code description

hyper secretion of ovarian androgen

5

Description of health condition studied

hirsutism

ICD-10 code

L68.0

ICD-10 code description

genital hair excess in female

Primary outcomes

1

Description

Menstrual disorders

Timepoint

6 month after implementation study

Method of measurement

questionnaire of Bleeding volume, number of days of spotting, Menstrual periods

2

Description

Body mass index

Timepoint

6 month after implementation study

Method of measurement

Weight in kilograms divided by the square of height in meters

3

Description

Hirsutism

Timepoint

6 month after implementation study

Method of measurement

Ferriman- Gullway score

Secondary outcomes

1

Description

Abdominal circumference

Timepoint

and 6 months after implementation of study

Method of measurement

The size of the margin around the narrowest part of the lower ribs and the iliac crest at the end of a normal exhalation

2

Description

Hip circumference.

Timepoint

6 months after implementation of study

Method of measurement

Hip circumference on the line that connects the two greater trochanter

3

Description

fasting blood sugar

Timepoint

6 months after implementation of study

Method of measurement

blood glucose levels after 8 hours fasting

Intervention groups

1

Description

intervention group : gives Omega 3 supplementation for 6 months.

Category

Treatment - Drugs

2

Description

control group : gives 2 placebo capsule daily for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Dr. Sajedhe Jafari

Street address

Al-Zahra hospital Isfahan, soffe avenue , Isfahan , Islamic Republic Of Iran 00989133681360 hb32us@yahoo.com

City

isfahan

2

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Dr. Sajedhe Jafari

Street address

Shahid Beheshti hospital , contra of aseman hotel, beside of Felezi bridge , Motahari avenue , Isfahan , Islamic Republic Of Iran 00989133681360 hb32us@yahoo.com

City

isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nemat bakhsh

Street address

Isfahan University of Medical Sciences , Isfahan , Islamic Republic Of Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Isfahan University of Medical Sciences

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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Sajedhe Jafari

Position

Assistant of Gynecology

Other areas of specialty/work**Street address**

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Fax**Email****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