Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 adouble blind prospective randomized clinical trial. The study population included women with polycystic ovary syndrome will referee 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 siences

Street address
isfahan, Hezar jerib avenue, Isfahan university of medical siences

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
menstural disorder

ICD-10 code
n92.6 , n9

ICD-10 code description
hypomenorrea 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 exess in female

Primary outcomes

1

Description
Menstrual disorders

Timepoint
6 mounth afther implementation study

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

2

Description
Body mass index

Timepoint
6 mounth afther implementation study

Method of measurement
Weight in kilograms divided by the square of height in meters

3

Description
Hirsutism

Timepoint

6 mounth afther implementation study

Method of measurement

Ferrimen- Gullway score

Secondary outcomes

1

Description

Abdominal circumference

Timepoint

and 6 mounths after implemention 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 mounths after implemention of study

Method of measurement

Hip circumference on the line that connects the two greater trochanter

3

Description

fasting blood sugare

Timepoint

6 mounths after implemention of study

Method of measurement

blood glucose levels after 8 hours fasting

Intervention groups

1

Description

intervention group : gives Omega 3 supplementation for 6 mounts.

Category

Treatment - Drugs

2

Description

control group : gives 2 placebo capsule daily for 6 mounts

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, besid 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 chancllor 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 chancllor 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 Siencese

Full name of responsible person
Dr. Sajedhe Jafari
Position
Assistant of Gynecology
Other areas of specialty/work
Street address
Isfahan
City
Isfahan
Postal code
73461-81746
Phone
+98 913 368 1360
Fax
Email
hb32us@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Siencese
Full name of responsible person
Dr. Behnaz Khani
Position
Gynecologist and Fellowship of Infertility
Other areas of specialty/work
Street address
Department of Obstetrics , School of Medicine , Isfahan University of Medical Sciences, Isfahan , Islamic Republic Of Iran 73461-81746 00983136687898
City
Isfahan
Postal code
73461-81746
Phone
+98 31 3668 7898
Fax
Email
khani@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Sajedeh Jafari
Position
Assistant of Gynecology
Other areas of specialty/work
Street address
Isfahan
City
Isfahan
Postal code
73461-81746
Phone
Fax
Email
hb32us@yahoo.com
Web page address
http://mui.ac.ir/

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