Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Omega3 supplementation on Visfatin, Adiponectin, and Anthropometric indices in women with polycystic ovary syndrome

Protocol summary

Summary

Aim of this study: Effect of Omega3 supplementation on Visfatin, Adiponectin, and Anthropometric indices in women with polycystic ovary syndrome.This study is Randomized, double-blind, controlled with placebo, single-center, second phase of trial .method: The study will be conducted on 64 women with polycystic ovary syndrome (20-40y) with a BMI 25-40, refer to Reproductive Science Institute and Shahid Sadoughi hospital. The exclusion criteria is Diabetes and Hypothyroid. After checking the inclusion criteria, and filling the consent form, they will be divided in to 2groups randomly. One group will take a capsules of Omega-3 (3 g/d) and control group take placebos for 2 month. Type of the study is Randomized Double Blind Placebo-controlled Clinical Trial. criteria inclusion: females 20-40years;PCOS diagnostic according to Roterdam criteria;BMI>25; No history about intake of any drug during the last 3 months that may affect the insulin sensitivity or hormonal profile such as: oral contraceptives, glucocorticoids, ovulation induction agents, anti diabetic and anti obesity drugs, estrogenic, antiandrogenic or anti hypertensive medication. Not being in any diet in the last 3month. Do not have any addiction to tobacco and alcohol; Do not taking a Omega-3 supplement in the last 3 month; Do not be menopause; Do not use anti-coagulant medicine or anti-depression medication; Do not be diabetic and hypothyroidism. exclusion criteria:Essentially needs for intake of OCP to treatment; Do not obey the Protocols of the study and do not digest more than 20% of supplements. Blood samples (adiponectin, visfatin,LH,FSH,prolactin) and Anthropometric indices are measured before and after intervention.

General information

Acronym

PCOS، LH، FSH

IRCT registration information

IRCT registration number: **IRCT2012071410281N1**
Registration date: **2012-09-09, 1391/06/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-09-09, 1391/06/19

Registrant information

Name

Hoorieh Daneshbodi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 9836

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h_daneshbodi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Institute for Reproductive Sciences, Research and Clinical Center for Infertility,Shahid Sadoughi University Of Medical Sciences and Health Services

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Omega3 supplementation on Visfatin, Adiponectin, and Anthropometric indices in women with polycystic ovary syndrome

Public title
Effect of Omega 3 supplementation in women with polycystic ovary syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
criteria inclusion: females 20-40years; PCOS diagnostic according to Roterdam criteria; BMI>25; No history about intake of any drug during the last 3 months that may affect the insulin sensitivity or hormonal profile such as: oral contraceptives, glucocorticoids, ovulation induction agents, anti diabetic and anti obesity drugs, estrogenic, antiandrogenic or anti hypertensive medication; Not being in any diet in the last 3month; Do not have any addiction to tobacco and alcohol; Do not taking a Omega-3 supplement in the last 3 month; Do not be menopause; Do not use anti-coagulant medicine; Do not use anti-depression medication; Do not be diabetic and hypothyroidism. exclusion criteria: Essentially needs for intake of OCP to treatment; Do not will to be in the study; Do not obey the Protocols of the study and do not digest more than 20% of supplements.
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid sadoughi university of medical sciences and health servicesInstitute for Reproductive Scienc
Street address
yazd-Safaeeye-Bouali avenue,infertility research center.
City
yzad
Postal code
8916877391
Approval date
2011-10-23, 1390/08/01
Ethics committee reference number
2162

Health conditions studied

1

Description of health condition studied
polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
serum visfatin-
Timepoint
before and after intervention
Method of measurement
visfatin ng/ml Elisa kit-

2

Description
serum adiponectin
Timepoint
before and after intervention
Method of measurement
adiponectin Elisa kit µg/ml-

3

Description
serum LH
Timepoint
before and after intervention
Method of measurement
LH Elisa kit U/l

4

Description
serum FSH
Timepoint
before and after intervention
Method of measurement
FSHElisa kit U/l-

5

Description
serum Prolactin
Timepoint
before and after intervention
Method of measurement
prolactin Elisa ng/mL

6

Description
body weight
Timepoint
before and after intervention
Method of measurement
leveled platform scale

7

Description
BMI-
Timepoint
before and after intervention
Method of measurement
leveled platform scale-stadiometer

8

Description
waist circumference
Timepoint
before and after intervention
Method of measurement
tape

9

Description
hip circumference
Timepoint
before and after intervention
Method of measurement
tape

Secondary outcomes

empty

Intervention groups

1

Description
intervention:capsules of fish-oil (3 g/d) for 2 month
Category
Placebo

2

Description
placebos of fish-oil (3 g/d) for 2 month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Institute for Reproductive Sciences, Research and clinical Center for Infertility
Full name of responsible person
Hoorieh Daneshbodi
Street address
yazd-Safaeeye-Bouali avenue,Institute for Reproductive Sciences, Research and clinical Center for Infertility
City
yazd

2

Recruitment center
Name of recruitment center
shahid sadoughi hospital
Full name of responsible person
Hoorieh Daneshbodi
Street address
Atlasi square-shahid ghandi Boulevard-ebne sina street
City
yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Institute for Reproductive Sciences, Research and clinical Center for Infertility
Full name of responsible person
Dr Ali Mohammad Abdoli
Street address
yazd-Safaeeye-Bouali avenue-Institute for Reproductive Sciences, Research and clinical Center for Infertility
City
yazd
Grant name
151450
Grant code / Reference number
151450
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Institute for Reproductive Sciences, Research and clinical Center for Infertility
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
Shahid sadoughi university of medical sciences and health services
Full name of responsible person
Hoorieh Daneshbodi
Position
-Executive-Ms,c student in nutrition and health science
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Person responsible for updating data

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Web page address

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