Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of omega3 supplementation on oxidated low density lipoprotein ,interleukin6 and hsCRP in women with polycystic ovary syndrome

Protocol summary

Summary

Objective: Effect of omega3 supplementation on oxidated low density lipoprotein ,interleukin6 and hsCRP in women with polycystic ovary syndrome. Sixty four women with PCOS(20-40 years) with a BMI >25 inclusion criteria/filling the consent form divide in to 2groups randomly. Capsules of fish-oil (3 g/d) and placebos for 2 month. Type of the study is Randomized Double Blind Placebo-controlled Clinical Trial. Blood samples oxidated low density lipoprotein, interleukin6 and hsCRP and androgens are measured in both groups before and after intervention

General information

Acronym

PCOS,oxLDL,SHBG,hsCRP

IRCT registration information

IRCT registration number: **IRCT201112318564N1**
Registration date: **2012-08-11, 1391/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-11, 1391/05/21

Registrant information

Name

Niloofar Vaziri

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Institute for Reproductive Sciences, Research and Cinical Center for Infertility

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 oxidated low density lipoprotein ,interleukin6 and hsCRP in women with polycystic ovary syndrome

Public title

Effect of omega3 supplementation in women with polycystic ovary syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: females 20-40 years; PCOS diagnostic according to Roterdam criteria and 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 months; do not be menopaused; do not use anti-coagulant medicine; do not use anti-depression medication and 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
Institute for Reproductive Sciences, Research and clinical Center for InfertilityShahid sadoughi uni

Street address
yazd-Safaeeye-Bouali avenue, Institute for Reproductive Sciences, Research and clinical Center for Infertility

City
yazd

Postal code
8916877391

Approval date
2011-10-23, 1390/08/01

Ethics committee reference number
2161

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
Oxidated low density lipoprotein

Timepoint
Before and after intervention

Method of measurement
OxLDL ng/ml Elisa kit -

2

Description
SHBG

Timepoint
Before and after intervention

Method of measurement
Elisa kit nmol/L SHBG- Elisa kit

3

Description
Free androgen index

Timepoint
Before and after intervention

Method of measurement
Testosteron/SHBG

4

Description
Testosteron

Timepoint
Before and after intervention

Method of measurement
Elisa kit nmol/L Testosteron

5

Description
Interleukin 6

Timepoint
Before and after intervention

Method of measurement
IL6 pg/ml Elisa kit

6

Description
hsCRP

Timepoint
Before and after intervention

Method of measurement
mg/L hsCRP - Elisa kit

Secondary outcomes

empty

Intervention groups

1

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

2

Description
Capsules of placebo (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
Niloofar Vaziri, MSc student in Nutrition and Health Sciences
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Yazd- Safaeeye- Bouali avenue-Institute for Reproductive Sciences, Research and clinical Center for Infertility
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2

Recruitment center
Name of recruitment center
Shahid Sadoughi hospital
Full name of responsible person
Niloofar Vaziri, MSc student in nutrition and health science
Street address
Yazd- Atlasi square- Shahid Ghandi Boulevard- Ebne sina street
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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
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Grant name
151643
Grant code / Reference number
151643
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
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Full name of responsible person
Niloofar Vaziri
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Person responsible for scientific inquiries

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Full name of responsible person
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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