

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

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

Protocol summary

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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

Recruitment status

Recruitment complete

Funding source

Institute for Reproductive Sciences, Research and Clinical 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

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

Nilloofar Vaziri

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 35 1836 7633

Email address

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 Rotterdam 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 menopausal; 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 Infertility Shahid 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

Street address

Yazd- Safaeeye- Bouali avenue-Institute for Reproductive Sciences, Research and clinical Center for Infertility

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Yazd

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

City

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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

Name of organization / entity

Institute for Reproductive Sciences, Research and Clinical Center for Infertility

Full name of responsible person

Niloofar Vaziri

Position

MSc student in nutrition and health science

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Assistant Professor

Other areas of specialty/work

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Other areas of specialty/work

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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