

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effects of oligopin supplementation on inflammatory and metabolic parameters in women with polycystic ovary syndrome.

Protocol summary

Study aim

Evaluation of the effects of Oligopin supplementation on inflammatory and metabolic profile in patients with polycystic ovary syndrome.

Design

Double blind randomized controlled trial

Settings and conduct

Eighty patients with PCOS (according to Androgen Excess Society criteria) without thyroid disease and androgenic hormone secretory tumors, at the age range of 18-40 years old will be randomly assigned to the groups receiving either oligopin or placebo (once a day) for 12 weeks. This randomized, double-blind trial will be conducted at Shariati hospital affiliated to Tehran University of Medical Sciences in the Iran. FSH, LH, SHBG, fasting blood sugar, insulin, HDL, LDL-C, total cholesterol, triglycerides, blood pressure, body composition, weight, height and waist circumferences will be measured before and 12 weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: PCOS diagnosis (according to Androgen Excess Society criteria); hyperandrogenism / hyperandrogenemia (testosterone >70ng/dl) and/or oligomenorrhea (<8 spontaneous menses per year) and/or polycystic ovarian morphology. Women aged from 18 to 40; Normal prolactin; thyroid function; 17-OH progesterone; No evidence of Androgenic hormone secretory tumors; No Cushing's syndrome or acromegaly
Exclusion criteria: Use of either oral contraceptives, steroids hormones or other medications that could modify the metabolism 1 months before the trial.

Intervention groups

Intervention group: oral intake of oligopine capsule (50 mg once daily) for 12 weeks. Control group: oral intake of placebo (once daily) for 12 weeks.

Main outcome variables

Follicle stimulating hormone (FSH); SHBG; C-peptide; hs-CRP; HDL-Cholesterol; LDL-Cholesterol; HbA1C; DHEA-S;

cholesterol; r Trigelisrid; BUN; luteinizing hormone (LH); Insulin; Testosterone ; TSH; Prolactin; blood sugar; Cratinine; alanine aminotransferase (ALT); aspartate aminotransferase (AST); alkaline phosphatase (ALP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140406017139N3**

Registration date: **2018-12-22, 1397/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-22, 1397/10/01**

Update count: **0**

Registration date

2018-12-22, 1397/10/01

Registrant information

Name

Mohammad Reza Mohajeri-tehrani

Name of organization / entity

Endocrinology and Metabolism Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0071

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of oligopin supplementation on inflammatory and metabolic parameters in women with polycystic ovary syndrome.

Public title
The effect of oligopin on PCOS

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
PCOS diagnosis according to Androgen Excess Society criteria: hyperandrogenism (hirsutism) / hyperandrogenemia (testosterone >70ng/dl) and/or oligomenorrhea (<8 spontaneous menses per year) and/or polycystic ovarian morphology on ultrasound Women aged from 18 to 40 years old Normal prolactin normal thyroid function 17-OH progesterone No evidence of Androgenic hormone secretory tumors No Cushing's syndrome or acromegaly
Exclusion criteria:
Using either oral contraceptives or steroids hormones during 1 month before the onset of the trial Using medications that could modify the metabolism during 1 month before the onset of the trial

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
block randomization method

Blinding (investigator's opinion)
Double blinded

Blinding description
The supplement and placebo will be prepared in identical shape, color and smell. Investigators and participants will be blind of the allocation process.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Endocrinology Metabolism Research Institute, Tehran University of Medical Scienc

Street address

Endocrinology & Metabolism Research Institute, 5th floor, Shariati Hospital, North Kargar Avenue

City

Tehran

Province

Tehran

Postal code

1411413137

Approval date

2017-11-30, 1396/09/09

Ethics committee reference number

IR.TUMS.EMRI.REC.1396.00163

Health conditions studied

1

Description of health condition studied

polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

S.H.B.G) Sex Hormon Binding Globolin)

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

2

Description

FSH

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

3

Description

LH

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

4

Description

fasting blood sugar

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

5

Description

testosterone

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

6

Description

DHEA-S

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

Secondary outcomes

1

Description

HDL-C

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

2

Description

LDL-C

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

3

Description

Total cholesterol

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

4

Description

TG

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

5

Description

Cr

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

6

Description

Hs-CRP

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

7

Description

HbA1C

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

8

Description

Insulin

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

9

Description

prolactin

Timepoint

Before and 12 weeks after the intervention

Method of measurement

ng/mL

10

Description

TSH

Timepoint

Before and 12 weeks after the intervention

Method of measurement

blood test

Intervention groups

1

Description

Intervention group: oral intake of oligopin (50mg capsule) after lunch, once a day for 12 weeks

Category

Treatment - Drugs

2**Description**

Control group: oral intake of placebo after lunch, once a day for 12 weeks.

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Endocrinology & Metabolism Research Institute

Full name of responsible person

Saeed Hosseini

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saeedhmdphd@hotmail.com

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Mostafa Qorbani

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Alborz University of Medical Sciences, North Taleqani Blvd, Taleqani Square

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Alborz University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

2**Sponsor****Name of organization / entity**

Endocrinology and Metabolism Research Institute

Full name of responsible person

Saeed Hosseini

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Email

saeedhmdphd@hotmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Endocrinology and Metabolism Research Institute

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Endocrinology and Metabolism Research Institute

Full name of responsible person

Saeed Hosseini

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Nutrition

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Email

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Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Saeed Hosseini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

Endocrinology & Metabolism Research Institute

Full name of responsible person

Asieh Mansour

Position

PhD. student

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data collected for the primary and secondary outcomes will be shared.

When the data will become available and for how long

access starting 18 months after publication

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of our study will only be accessible by other researchers, for conducting Meta-analysis.

From where data/document is obtainable

To access the required data, the researchers can contact Ms. Asieh Mansour: email address:asiehmansour@yahoo.com

What processes are involved for a request to access data/document

The researcher should provide a brief description of the aims of his study. The request will be assessed by the researchers, and if we agree to the request, the requested data will be emailed.

Comments