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 Oligpin 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-Cholestrol; LDL-Cholestrol; HbA1C; DHEA-S; cholestrol; 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
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Iran (Islamic Republic of)
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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 centers

1

Recruitment center
Name of recruitment center
Endocrinology & Metabolism Research Institute
Full name of responsible person
Saeed Hosseini
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Sponsors / Funding sources

1

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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
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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
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
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Position
Assistant professor

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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