

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of sativa *Nigella sativa* oil on serum levels of IL-6, TNF- alpha, insulin and lipid profiles in patients with polycystic ovarian syndrome

Protocol summary

Study aim

Determining the effect of black seed oil on serum levels of IL-6, TNF- α , insulin, fasting blood sugar, insulin resistance, insulin sensitivity and lipid profile in patients with polycystic ovary syndrome.

Design

The study is conducted in an interventional way (Phase 3 clinical trial) and on 60 patients with polycystic syndrome. Patients will be randomly divided into two groups of 30 using envelopes containing medicine and placebo and two blinders. The case group will be given black seed oil at a dose of 1000 mg daily for 12 weeks, and the control group will be given a placebo drug at the same dose and time.

Settings and conduct

The study is conducted on 60 patients with polycystic syndrome referred to the Obstetrics and Gynecology Clinic of Alavi Hospital in Ardabil. Patients will be randomly divided into two groups. Black seed oil will be given to the case group for 12 weeks and placebo to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Menstrual cycle disorders, clinical or biochemical hyperandrogenism and sonographic appearance of polycystic syndrome Exclusion criteria: Type 2 diabetes, adrenal hyperplasia, thyroid disease, autoimmune diseases and hyperprolactinemia, diet and special drug use

Intervention groups

The case group received 12 weeks of black seed oil with a dose of 1000 mg daily and the placebo drug control group with the same dose and time.

Main outcome variables

Interleukin 6, TNF-alpha, insulin, fasting blood sugar, insulin sensitivity index, insulin resistance index, Lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230125057222N1**

Registration date: **2023-08-19, 1402/05/28**

Registration timing: **prospective**

Last update: **2023-08-19, 1402/05/28**

Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Samaneh Jamshidian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-07, 1402/06/16

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sativa Nigella sativa oil on serum levels of IL-6, TNF- alpha, insulin and lipid profiles in patients with polycystic ovarian syndrome

Public title

Effect of Nigella sativa oil in patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Oligomenorrhea or lack of ovulation Polycystic ovaries based on ultrasound Androgenic hormone changes in laboratory or clinical form (the presence of hirsutism)

Exclusion criteria:

Type 2 diabetes - thyroid disease - adrenal hyperplasia autoimmune diseases - hyperprolactinemia People with structured physical activity or scheduled exercise If three months before entering the study, they use a special diet or special drugs that may affect the results, they will be excluded from the study, such as anti-obesity drugs, ovulation stimulants, antidepressants, insulin sensitivity, oral contraceptives, aspirin, and Anti-prostaglandin drugs If there are signs of pregnancy, they will be excluded from the study

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Using envelopes (A and B) containing medicine and placebo, they will be randomly divided into two groups. Based on the calculated sample size, 30 envelopes A and 30 envelopes B are placed in a lottery container, and then the envelopes are randomly removed from the container without replacement and the created sequence will be recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, double-blind will be used so that the patient and the student who provides the envelope to the patient will be blind to the content of the envelopes (intervention or placebo).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

Street address

Faculty of Medicine, 1st floor, University Street, 8599156189, Ardabil, Iran

City

Ardabil

Province

Ardabil

Postal code

8599156189

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.ARUMS.REC.1401.215

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Interleukin 6,

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Determination of serum level

2

Description

TNF-alpha

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Determination of serum level

3

Description

lipid profile

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Determination of serum level

4

Description

insulin

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Determination of serum level

5

Description

fasting blood sugar

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Determination of serum level

Secondary outcomes

1

Description

Insulin resistance index (QUICKI), insulin sensitivity index (HOMA-IR)

Timepoint

Before and 12 weeks after the intervention

Method of measurement

Calculation of indices

Intervention groups

1

Description

Intervention group: subjects receiving black seed oil. In this group, subjects will receive capsules containing black seed oil with a dose of 1000 mg per day orally for three months. Black seed oil capsules will be provided by Barij Essential Oil Company (Kashan).

Category

Treatment - Drugs

2

Description

Control group: Subjects receiving placebo capsules. In this group, subjects will receive capsules containing placebo, which are similar to capsules containing black seed oil in terms of shape, color and side ingredients, orally daily for three months. Placebo capsules will be provided from Barij Essan Company (Kashan).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Ardabil Hospital

Full name of responsible person

Faranak Jalilvand

Street address

Sports field - Alavi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

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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

Ardabil University of Medical Sciences

Proportion provided by this source

80

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

Ardabil University of Medical Sciences

Full name of responsible person

Faranak Jalilvand

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Samaneh Jamshidian

Position

Resident women

Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic, clinical and outcome data

When the data will become available and for how long

No time limit

To whom data/document is available

Journal if needed

Under which criteria data/document could be used

With permission from the University Ethics Committee

From where data/document is obtainable

Corresponding

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

A written request from the relevant unit and permission from the university's ethics committee

Comments