# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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)

**Phone**

+98 45 3324 8888

**Email address**

jamshidian.925@gmail.com

**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

**City**

Ardabil

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**Postal code**

5613974156

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+98 45 3324 8888

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faran.jalil@gmail.com

## 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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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
Samaneh Jamshidian

**Position**
Resident women

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Gynecology and Obstetrics

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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**