

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

A comparison between the effects of modified Nigella Sativa capsules and a placebo on menstruation occurrence, and the menstrual bleeding duration and volume in polycystic ovary patients with oligomenorrhea and amenorrheae: a randomized double blind clinical trial

Protocol summary

Summary

This is a double blind randomized clinical trial with placebo in which we evaluate the effect of modified Nigella Sativa capsule on the menstrual bleeding frequency, duration and volume in Poly Cystic Ovary (PCO) patients with oligomenorrhea or amenorrhea and compared it with those of placebo. This is a multi-central trial. According to the National Institute of Health criteria, the gynecologist selects eligible women with PCO with oligomenorrhea or amenorrhea; candidates enter the study if do not have any other systemic disease (e.g., diabetes, hyperprolactinemia, thyroid disorders, chronic liver and kidney diseases, and epilepsy) be pregnant or lactating. A sample of 68 patients will randomly be divided into two groups of 34, one group will receive the Nigella Sativa and the other one placebo capsule. First, the hormonal and biochemical tests will be performed on all patients, which will be repeated at the end of the study for patients who show abnormal results. A 2 g/day Black Cumin, 4 capsules of 500 mg, will be taken two times per day for one month. The medication will be stopped if menstruation occurs. The treatment duration will be three months; the medication consumption must be delayed for one week in case the menstruation does not occur, resulting in a four-month treatment duration. The placebo will be prescribed the same as the Nigella Sativa capsule, i.e. 4 capsules for a total of 2 grams. The outcomes of this study are menstruation frequency and the menstrual bleeding duration and volume.

General information

Acronym

PCOS

IRCT registration information

IRCT registration number: **IRCT2016041827455N1**

Registration date: **2016-06-19, 1395/03/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-19, 1395/03/30

Registrant information

Name

Seyedeh Atieh Naeimi

Name of organization / entity

Traditional Medicine School of Shahid Beheshti
University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8877 3521

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-12-28, 1394/10/07

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effects of modified Nigella Sativa capsules and a placebo on menstruation occurrence, and the menstrual bleeding duration and volume in polycystic ovary patients with oligomenorrhea and amenorrhea: a randomized double blind clinical trial	
Public title	The effect of Nigella Sativa on oligomenorrhea and amenorrhea in patients with polycystic ovary syndrome
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Diagnosis of Polycystic Ovary syndrome by gynecologist, according to the National Institute of Health's criteria; women aged 18-38 years old with irregular periods; having informed consent; Non-consumer of any hormonal medication and Metformin for at least three months prior the study. Exclusion criteria: Using anti-hypertensive, anti-cholesterol, anti-diabetic, insulin-sensitizing, medication; using aspirin and other anti-clotting medications, oral contraceptive and the anti-prostaglandin medications, parallel consumption of other herbal medications for disease treatment; patient with uncontrolled high blood pressure history, brain stroke, heart attack, cancer, cardiovascular disorders, liver disease, renal and thyroid disorders, type 1 or 2 diabetes; pregnancy and lactation; smoking.
Age	From 18 years old to 38 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 68
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	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee in Biomedical research, Shahid Beheshti University of Medical Sciences (IR.SBMU.REC
Street address	Side of Taleghani Hospital, Evin, Shahid Chamran Highway, Tehran
City	Tehran
Postal code	
Approval date	2015-12-27, 1394/10/06
Ethics committee reference number	IR.SBMU.REC.1394.157
Health conditions studied	
<u>1</u>	
Description of health condition studied	Polycystic ovarian syndrome
ICD-10 code	E28.2
ICD-10 code description	Polycystic ovarian syndrome
Primary outcomes	
<u>1</u>	
Description	Occurance of Menstrual bleeding
Timepoint	Before the intervention, 1, 2, 3 and 4 months after the intervention.
Method of measurement	Ask the patient
<u>2</u>	
Description	Duration of menstrual bleeding
Timepoint	Before intervention and 1, 2, 3, 4 month after intervention
Method of measurement	Ask the patient and complete tracking form
<u>3</u>	
Description	Menstrual blood volume
Timepoint	Before intervention and 1, 2, 3, 4 month after intervention
Method of measurement	Pictorial Blood Loss Assessment Chart (PBAC)
Secondary outcomes	
<u>1</u>	
Description	Menstrual cycle length
Timepoint	Before intervention and 1, 2, 3, 4 month after intervention
Method of measurement	Ask the patient and complete tracking form

2

Description

serum LH

Timepoint

Before intervention and 3 month after intervention

Method of measurement

Serum analysis by ELIZA

3

Description

Total Testosterone

Timepoint

Before intervention and 3 month after intervention

Method of measurement

Serum analysis by ELIZA

Intervention groups

1

Description

Group 1:Nigella Sativa capsule, 4 capsules 500 mg, 2 in the morning and 2 nights during the month, except during the period. if the bleeding did not happen in a month,the drug would be cut off for a week

Category

Treatment - Drugs

2

Description

Group 2: control group who received placebo from starch capsules, 4 capsules 500 mg, 2 in the morning and 2 nights during the month, except during the period if the bleeding did not happen in a month,the drug would be cut off for a week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Seyedeh Atieh Naeimi

Street address

No.8 Shams Alley, opposite Tavanir station, Vali Asr
Street, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Private clinic of Mrs Soodabe Bioos

Full name of responsible person

Seyedeh Atieh Naeimi

Street address

Charmardan Street, Qom

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Dr. Mahmood Mosaddegh

Street address

No.8 Shams Alley, Opposite Tavanir station, Vali Asr
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City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences

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

School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Seyedeh Atieh Naeimi

Position

Ph.D student of Traditional Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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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