

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)

Phone

+98 21 8877 3521

Email address

naimi@guilan.ac.ir

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		Street address Side of Taleghani Hospital, Evin, Shahid Chamran Highway, Tehran	
Public title The effect of Nigella Sativa on oligomenorrhea and amenorrhea in patients with polycystic ovary syndrome		City Tehran	
Purpose Treatment		Postal code Approval date 2015-12-27, 1394/10/06	
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.		Ethics committee reference number IR.SBMU.REC.1394.157	
Age From 18 years old to 38 years old		Health conditions studied	
Gender Female		1 Description of health condition studied Polycystic ovarian syndrome	
Phase N/A		ICD-10 code E28.2	
Groups that have been masked No information		ICD-10 code description Polycystic ovarian syndrome	
Sample size Target sample size: 68		Primary outcomes	
Randomization (investigator's opinion) Randomized		1 Description Occurance of Menstrual bleeding	
Randomization description		Timepoint Before the intervention, 1, 2, 3 and 4 months after the intervention.	
Blinding (investigator's opinion) Double blinded		Method of measurement Ask the patient	
Blinding description		2 Description Duration of menstrual bleeding	
Placebo Used		Timepoint Before intervention and 1, 2, 3, 4 month after intervention	
Assignment Parallel		Method of measurement Ask the patient and complete tracking form	
Other design features		3 Description Menstrual blood volume	
Secondary Ids empty		Timepoint Before intervention and 1, 2, 3, 4 month after intervention	
Ethics committees		Method of measurement Pictorial Blood Loss Assessment Chart (PBAC)	
1 Ethics committee Name of ethics committee Ethics Committee in Biomedical research, Shahid Beheshti University of Medical Sciences (IR.SBMU.REC		Secondary outcomes	
		1 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
Street, Tehran

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

Street address

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

City

Tehran

Postal code

Phone

+98 21 8877 3521

Fax

Email

naimi@guilan.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Mojgan Tansaz M.D

Position

Traditional medicine specialist, Assistant Professor

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 21 8877 3521

Fax

Email

Tansaz@sbmu.ac.ir, Tansaz_mojgan@yahoo.com

Web page address

Person responsible for updating data

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

Street address

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

City

Tehran

Postal code

Phone

+98 21 8877 3521

Fax

Email

naimi@guilan.ac.ir

Web page address

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