

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 2026

The effect of capsules Nigella sativa seeds on the severity of symptoms of Premenstrual syndrome

Protocol summary

Summary

1. Objective: Determination and comparison of the severity of physical and behavioral symptoms of Premenstrual syndrome in the intervention and control groups before and after the study at the end of the first and second months. 2. Design: This study was a double-blind clinical trial conducting. 3. Setting and conduct: Research units with Inclusion criteria easy sampling was after completing the list of questionnaire and obtaining informed consent of subjects enrolled in research and they will be asked Calendar of Premenstrual Experience at the end of each day and the amount of menstrual cycle (during bleeding days Menstruation) completed the in two cycles of control and then delivered to researcher. Research units are allocated into Nigella sativa seeds and Placebo groups using random numbers table and had given Nigella sativa seeds and Placebo capsules that their nature is identified with the letters A and B will be marked only for pharmacist consultant to be delivered to research units. They use from 7 days before the start of menstrual bleeding to 3 days menstrual bleeding in first and second cycle intervention and complete the questionnaire and to submit researcher. 4. Participants including major eligibility criteria: Students studying at Mashhad University of Medical Sciences and residing in a dormitory suffering from Premenstrual syndrome with: Inclusion criteria: Aged between 18 and 35; Regular and normal menstruation. Exclusion criteria: Pregnancy and lactation; Any history disorders; Any drug use; Smoking or drinking alcohol; Professional athlete; Depression and Anxiety and extreme stress; Use of traditional medicine methods to reduce the physical and behavioral symptoms of premenstrual syndrome ; BMI ≥ 30 . 5. Intervention: Intervention group: Consumption of Nigella sativa seeds capsules to the 1,500 mg orally daily (3 capsules of 500 mg in 3 doses every 8 hours on a full stomach) from 7 days before the start of menstrual bleeding to 3 days menstrual bleeding will be given for 2 cycles. Control group: Consumption of Placebo capsules

to the 1,500 mg orally daily (3 capsules of 500 mg in 3 doses every 8 hours on a full stomach) from 7 days before the start of menstrual bleeding to 3 days menstrual bleeding will be given for 2 cycles. 6. Main outcome measures (variables): The Severity of physical and behavioral symptoms of premenstrual syndrome.

General information

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT2017011131881N1**

Registration date: **2017-07-08, 1396/04/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-08, 1396/04/17

Registrant information

Name

Samaneh Maskani

Name of organization / entity

School of Nursing and Midwifery, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 1276

Email address

maskanis931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-01-22, 1395/11/03

Expected recruitment end date

2017-06-24, 1396/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of capsules Nigella sativa seeds on the severity of symptoms of Premenstrual syndrome

Public title

The effect of capsules Nigella sativa seeds on the Premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Student studying at Mashhad University of Medical Sciences and residing in a dormitory; Iranian and Muslim; Aged between 18 and 35; Regular & normal menstruation; And having premenstrual syndrome. Exclusion criteria: Pregnancy and lactation; Any history disorders; Any drug use; Smoking or drinking alcohol; Professional athlete; Depression and Anxiety and extreme stress; Use of traditional medicine methods to reduce the physical and behavioral symptoms of premenstrual syndrome ; BMI ≥ 30 .

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences Ethics Committee

Street address

University Ave

City

Mashhad

Postal code**Approval date**

2017-01-09, 1395/10/20

Ethics committee reference number

IR.MUMS.REC.1395.484

Health conditions studied**1****Description of health condition studied**

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes**1****Description**

The severity of physical symptoms of Premenstrual syndrome

Timepoint

Day 2 cycles before the intervention. 2 cycles after the intervention

Method of measurement

Questionnaire COPE

Secondary outcomes**1****Description**

The Severity of behavioral symptoms of Premenstrual syndrome

Timepoint

Day 2 cycles before the intervention. 2 cycles after the intervention

Method of measurement

Questionnaire COPE

Intervention groups**1****Description**

Intervention group: Consumption of Nigella sativa seeds capsules to the 1,500 mg orally daily (3 capsules of 500 mg in 3 doses every 8 hours on a full stomach) from 7 days before the start of menstrual bleeding to 3 days

menstrual bleeding will be given for 2 cycles.

Category

Treatment - Drugs

2

Description

Control group: Consumption of Placebo capsules to the 1,500 mg orally daily (3 capsules of 500 mg in 3 doses every 8 hours on a full stomach) from 7 days before the start of menstrual bleeding to 3 days menstrual bleeding will be given for 2 cycles.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences dormitories

Full name of responsible person

Samaneh Maskani

Street address

Bahonar avenue, dormitory Pardis

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

University Ave

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Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad 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 Nursing and Midwifery, Mashhad University of Medical Sciences

Full name of responsible person

Samaneh Maskani

Position

Master of Midwifery Student

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Mashhad University of Medical Sciences

Full name of responsible person

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Position

Lecture, Department of Midwifery, Master of Midwifery

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Samaneh Maskani

Position

Master of Midwifery Student

Other areas of specialty/work

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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