

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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  $\geq 30$ . 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  $\geq 30$ .

**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**

Daily 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**

Daily 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

**City**

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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**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**

Mahin Tafazoli

**Position**

Lecture, Department of Midwifery, Master of Midwifery

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Samaneh Maskani

**Position**

Master of Midwifery Student

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+98 51 4423 2362

**Email**

Maskanis931@mums.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*