Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Calender 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 befor 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 befor 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 befor 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
Daiy 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
Daiy 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 befor 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 befor 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

Street address

No 8, Eram 13 Alley, Eram Avenue.

City

Sabzevar

Postal code

9618673991

Phone

+98 51 4464 1276

Fax

+98 51 4423 2362

Email

Maskanis931@mums.ac.ir

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

Mahin Tafazoli

Position

Lecture, Department of Midwifery, Master of Midwifery

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Mashhad University of Medical Sciences, Ebnecina Avenue

City

Mashhad

Postal code

Phone

+98 51385981511

Fax

Email

Tafazolim@mums.ac.ir

Web page address

Person responsible for updating data

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

Street address
No 8, Eram 13 Alley, Eram Avenue.
City
Sabzevar
Postal code
9618673991
Phone
+98 51 4464 1276
Fax
+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