Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the effect of black seed capsules and vitamin B6 on the severity of premenstrual syndrome symptoms in students

Protocol summary

Study aim
Comparative study of Nigella sativa Seeds Capsules and vitamin B6 on the severity of premenstrual syndrome symptoms in students

Design
The clinical trial had 3 control, intervention, and placebo groups with parallel groups, randomized on 105 patients, and a randomization block design with size 6 was used for randomization (using the computer program Createa blocked randomization list with the link https://www.sealedenvelope.com/simple-randomiser/v1/lists).

Settings and conduct
This triple-blind randomized clinical trial study will be conducted on 105 students with premenstrual syndrome living in the dormitories of Rafsanjan University of Medical Sciences in 2024.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1) Being single 2) Willingness to participate in the study 3) Completing a written informed consent form 4) Age 18 to 35 years 5) Having regular menstruation of 21 to 35 days 6) Bleeding duration of 3 to 10 days 7) Obtaining a score of 33-64 from the Premenstrual Syndrome Assessment Questionnaire Exclusion criteria 8) Having a specific underlying disease (diabetes, blood pressure, thyroid instability) and diseases of the reproductive system 9) Taking medications that affect premenstrual syndrome, antidepressants, birth control pills and hormones 10) The occurrence of stressful events such as the death of a loved one within the past year 11) Smoking 12) The occurrence of complications or drug allergies 13) Regular exercise

Intervention groups
Intervention: black seed consumption, control: vitamin B6 consumption, placebo: no drug consumption

Main outcome variables
Reducing symptoms of the syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240614062131N1**
Registration date: **2025-03-21, 1404/01/01**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-21, 1404/01/01**
Update count: **0**

Registration date
2025-03-21, 1404/01/01

Registrant information
Name
Elham kabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 3377 2356
Email address
elhamkabi56@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-29, 1403/10/09

Expected recruitment end date
2025-05-30, 1404/03/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparative study of the effect of black seed capsules and vitamin B6 on the severity of premenstrual syndrome symptoms in students

Public title
Comparative study of the effect of black seed capsules and vitamin B6 on the severity of premenstrual syndrome symptoms in students
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being single Willingness to participate in the study Completed a written informed consent form Age 18 to 35 years Having a regular menstrual cycle of 21 to 35 days Bleeding duration of 3 to 10 days Obtaining a score of 33-64 on the Premenstrual Syndrome Assessment Questionnaire
Exclusion criteria:
Unwillingness to participate in the study
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: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
They were divided into 3 groups of 35 people (vitamin B6 capsules, black seed capsules, and placebo) in a random block design with a size of 6 (using the computer program Createa blocked randomization list with the link https://www.sealedenvelope.com/simple-randomiser/v1/lists).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Rafsanjan University of Medical Sciences
Street address
Central Organization- Imam Ali (AS) Boulevard
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2024-12-02, 1403/09/12
Ethics committee reference number
IR.RUMS.REC.1403.142

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
Premenstrual syndrome score from the questionnaire
Timepoint
At the beginning of the study (before the intervention) and one month and two months after the end of the intervention
Method of measurement
Premenstrual Syndrome Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Black seed oil capsules 500 mg, 2 per day, in two menstrual cycles, from 3 days before menstruation to 1 day after menstruation, Barij Essential Oil Company
Category
Treatment - Drugs

2

Description
Intervention group: 40 mg vitamin B6 capsules, 2 per day, in two menstrual cycles, from 3 days before menstruation to 1 day after menstruation, Galenus Company
Category
Treatment - Drugs

3

Description
Control group: Placebo, 500 mg starch capsules, 2 per day, from 3 days before menstruation to 1 day after menstruation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Student dormitories of Rafsanjan University of Medical Sciences
Full name of responsible person
Marzieh Najjar
Street address
Central Organization-Imam Ali (AS) Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Reza Vazirinejad
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Marzieh Najar
Position
academic board
Latest degree
Master
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Person responsible for updating data

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Elham Kabi

Position
Midwife

Latest degree
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Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Article

When the data will become available and for how long
Print article 1404

To whom data/document is available
All people

Under which criteria data/document could be used
Other articles

From where data/document is obtainable
Journal site

What processes are involved for a request to access data/document
Email and journal website

Comments