Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the effect of Vitagnus capsules, Soy and the combination of Vitagnus and Soy in students with premenstrual syndrome

Protocol summary

Study aim
Comparison of the effects of Vitagnus capsule, Soy and the combination of Vitagnus and Soy in students with premenstrual syndrome (PMS)

Design
A three-group, randomized double-blind clinical trial

Settings and conduct
This Double-blind and three-group research will be conducted on 108 students living in the dormitory of Mashhad University of Medical Sciences with moderate to severe PMS symptoms. The existence of PMS by the temporary diagnosis form of PMS and the absence of depression, anxiety and severe stress according to the DASS-21 questionnaire were selected as the research unit, and a written consent form will be obtained from them to participate in the study. Then the COPE form will be given to the sample to confirm the diagnosis and severity of PMS for two consecutive menstrual cycles; If the average symptom intensity score is more than 30%, the sample will be included in the study and the people of the research unit will be given Vitagnus capsules, Soy capsules and combined Vitagnus and Soy capsules once a day after breakfast throughout the cycle for 2 menstrual cycles. Within 2 cycles of treatment, a daily condition registration form will be collected and the average intensity of physical, mental and general symptoms as well as the intensity of menstrual pain will be measured in the two cycles before and after the intervention.

Participants/Inclusion and exclusion criteria
Entry criteria: Student living in the dormitory of Mashhad University of Medical Sciences؛ written consent to participate in the study؛ being single؛ age 16-45 years؛ regular menstruation؛ BMI less than 30 kg/m2؛ having symptoms of PMS and Exclusion criteria: Allergy to Vitagnus and Soy products

Intervention groups
3 groups receiving 500 mg capsules, including Vitagnus capsules, Soy capsules, and combined Vitagnus and Soy capsules

Main outcome variables
Average score of physical, mental and total PMS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220720055514N1**
Registration date: **2022-08-30, 1401/06/08**
Registration timing: **prospective**

Last update: **2022-08-30, 1401/06/08**
Update count: **0**

Registration date
2022-08-30, 1401/06/08

Registrant information

Name
Roya Partovigolshan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 4262 1034

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partovigr992@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-06, 1401/06/15

Expected recruitment end date
2023-04-20, 1402/01/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Vitagnus capsules, Soy and the combination of Vitagnus and Soy in students with premenstrual syndrome

Public title

Comparison of the effect of Vitagnus capsules, Soy and the combination of Vitagnus and Soy in students with premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be a student living in the dormitory of Mashhad University of Medical Sciences Have written and informed consent to participate in the study Be of Iranian and Muslim nationality Be single Be 16-45 years old Have regular menstruation with menstrual intervals of 21-38 days and a bleeding period of less than 7 days Have a BMI less than 30 kg/m2 Have 5 or more than 5 symptoms out of 11 symptoms of the premenstrual syndrome temporary diagnosis form and at least one of the first 4 symptoms of the questionnaire Do not suffer from physical or mental illness Do not suffer from severe Depression, Stress and Anxiety according to DASS 21 form Not taking any special medicine She has not taken effective drugs (chemical or herbal) on premenstrual syndrome in the last three months Has not experienced an unfortunate accident in the last 6 months Not a professional athlete Do not follow a special diet or vegetarian diet Not allergic to Vitagnus and Soy products No history of breast cancer in first degree relatives Do not consume Alcohol, Cigarettes or any drugs

Exclusion criteria:

Get married while studying Complications or allergies to Vitagnus medicine, Soy, or the combination of Vitagnus and Soy occur Experienced any unfortunate incident while studying Suffer physical and mental illness while studying Do not use any type of treatment to relieve symptoms of PMS during the study period Do not complete the daily symptom registration questionnaire or complete the form incompletely Do not use the medicine according to the instructions and opinion of the pharmacologist Do not want to continue taking medicine and cooperate in the plan

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to guarantee an equal number of study subjects in two groups, random permutation block method is determined using the website www.sealedenvelope.com. In this way, a number of 4-member blocks are created by accident through the above site. For example, the blocks can be as follows: [ABCABC], [BACBAC], [CACBAB], ...

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind so that the researcher and the participants will not know which group each person will be placed in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Qureshi Building., University Street., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9173595199

Approval date

2022-07-19, 1401/04/28

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.055

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 mean score of severity of physical, mental and total premenstrual syndrome by the premenstrual events calendar form (COPE)

Timepoint
The average symptom severity score at the end of the first and second cycles after the intervention compared to before the intervention in the three groups receiving Vitagnus capsules, Soy and the combination of Vitagnus and Soy

Method of measurement
Premenstrual Events Calendar Questionnaire (COPE)

Secondary outcomes

1

Description
Dysmenorrhea or menstrual pain

Timepoint
The average score of menstrual pain intensity at the end of the first and second cycles after the intervention compared to before the intervention in three groups receiving Vitagnus capsules, Soy and the combination of Vitagnus and Soy

Method of measurement
Visual Pain Scale Questionnaire (VAS)

Intervention groups

1

Description
The first intervention group: 500 mg Vitagnus and soy combined capsule, containing 20 mg dry extract of Vitex agnus-castus and 250 mg Soy powder, once a day after breakfast for 2 consecutive menstrual cycles.

Category
Prevention

2

Description
The second intervention group: Vitagnus 500 mg capsule, containing 40 mg dry extract of Vitex agnus-castus, once a day after breakfast for 2 consecutive menstrual cycles.

Category
Prevention

3

Description
The third intervention group: 500 mg Soy capsule, containing 500 mg soy powder, once a day after breakfast for 2 consecutive menstrual cycles.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hostel of Mashhad University of Medical Sciences

Full name of responsible person
Seid-Ahmad Mousavi-Kakhki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Majid Ghayyur Mobarahan

Street address
Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences Qureshi., Building., University St

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Grant name
Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences

Grant code / Reference number
4010512

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

Title of funding source
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Roya Partovigolshan

Position

midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Maryam Moradi

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Roya Partovigolshan

Position

Master's degree student of midwifery

Latest degree

Bachelor

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Publication of research results in the form of scientific article printining

When the data will become available and for how long

data will become available after publication of the

To whom data/document is available

The general public and all researchers

Under which criteria data/document could be used

For use in the treatment of premenstrual syndrome and scientific use based on the article

From where data/document is obtainable

En Dr. Maryam Moradi, Assistant Professor, Mashhad School of Midwifery Nursing, e-mail:

moradim@mums.ac.ir

What processes are involved for a request to access data/document

Request to access data through email and request will be assessed by the research team.

Comments