Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of frankincense capsules on premenstrual syndrome and primary dysmenorrhea of students of Mashhad University of Medical Sciences

Protocol summary

Study aim

Determining the effect of frankincense capsules on PMS and primary dysmenorrhea

Design

A controlled, parallel-group, triple-blind, randomized, phase 2 clinical trial on 62 patients. PASS software will be used for randomization.

Settings and conduct

Sampling will be done in the hostels of Mashhad University of Medical Sciences. Both intervention and control groups are monitored for 2 months in order to diagnose dysmenorrhea and premenstrual syndrome. people will receive three 500 mg capsules daily for 2 cycles from 7 days before the start of menstruation to the first 3 days of menstruation. Pain intensity by VAS scale And the duration of pain by Cox scale will be recorded .The symptoms of premenstrual syndrome will be measured by COPE form. Finally, the symptoms of PMS and the severity and duration of dysmenorrhea before, one and two months after the intervention will be compared with the control group.

Participants/Inclusion and exclusion criteria

1.Age 18 to 35.2.Regular menstrual cycles.3.Suffering from PMS and primary moderate to severe dysmenorrhea at the same time.4.single.5.Resident in the dormitory.6.Not taking certain drugs.7.Not using alcohol or drugs and tobacco.8.Not having depression, anxiety and extreme stress.9.Lack of diet.10.Not using medicinal and traditional treatments to reduce the symptoms of PMS and dysmenorrhea.11.BMI less than 30.12.Absence of specific medical disease.13.Absence of known gynecological issues.14.The absence of stressful events in the past 6 months.15.Not engaging in sports professionally.

Intervention groups

The intervention group receive frankincense capsules (500 mg) 3 times a day from 7 days before the onset of menstruation to the first 3 days of menstruation for 2 months.The control group will receive the placebo capsule.

Main outcome variables

Average total score of premenstrual syndrome symptoms and severity and duration of dysmenorrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230702058648N1**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**
Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Mohaddeseh Borhaninasab

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of frankincense capsules on premenstrual syndrome and primary dysmenorrhea of students of Mashhad University of Medical Sciences

Public title

Investigating the effect of frankincense capsules on premenstrual syndrome and menstrual pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Age 18 to 35 years. 2. Regular menstrual cycles. 3. Suffering from premenstrual syndrome and primary moderate to severe dysmenorrhea at the same time. 4. Being single. 5. Resident in the dormitory of Mashhad University of Medical Sciences. 6. Not taking certain drugs. 7. Not using alcohol or drugs and tobacco. 8. Not having depression, anxiety and extreme stress. 9. Lack of diet. 10. Not using medicinal and traditional treatments to reduce the symptoms of premenstrual syndrome and dysmenorrhea. 11. BMI less than 30. 12. Absence of specific medical disease. 13. Absence of known gynecological issues such as fibroids and endometriosis. 14. The absence of stressful events in the past 6 months. 15. Not engaging in sports professionally.

Exclusion criteria:

1. Age 18 to 35 years. 2. Regular menstrual cycles. 3. Suffering from premenstrual syndrome and primary moderate to severe dysmenorrhea at the same time. 4. Being single. 5. Resident in the dormitory of Mashhad University of Medical Sciences. 6. Not taking certain drugs. 7. Not using alcohol or drugs and tobacco. 8. Not having depression, anxiety and extreme stress. 9. Lack of diet. 10. Not using medicinal and traditional treatments to reduce the symptoms of premenstrual syndrome and dysmenorrhea. 11. BMI less than 30. 12. Absence of specific medical disease. 13. Absence of known gynecological issues such as fibroids and endometriosis. 14. The absence of stressful events in the past 6 months. 15. Not engaging in sports professionally.

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple. Allocation Concealment method: In order to conceal, frankincense and placebo oral capsules are provided to the researcher by the pharmacist consultant in similar forms (appearance, color and packaging) and with two different codes, and only the pharmacist consultant knows about it. The method used to generate a random allocation sequence by mentioning the name of the software or site used: After confirming the presence of premenstrual syndrome and early dysmenorrhea in the research units and according to the entry and exit criteria, people will be randomly assigned to two groups using the PASS software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Allocation Concealment method: In order to conceal, frankincense and placebo oral capsules are provided to the researcher by the pharmacist consultant in similar forms (appearance, color and packaging) and with two different codes, and only the pharmacist consultant knows about it.

Placebo

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

Mashhad Faculty of Nursing and Midwifery, Ibn-e Sina St., Doktora Crossing., Mashhad., Iran

City

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Province

Razavi Khorasan

Postal code

9137913199

Approval date

2023-07-25, 1402/05/03

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.065

Health conditions studied

1

Description of health condition studied

Dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

2

Description of health condition studied

Premenstrual Syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

Average total score of premenstrual syndrome symptoms

Timepoint

Calculation of the average score of premenstrual syndrome symptoms at the beginning of the study (before the start of the intervention) and 1 and 2 months after the start of the intervention

Method of measurement

The mean total score of premenstrual syndrome symptoms will be evaluated by the Calendar of Premenstrual Events (COPE) form, as self-reported by the patients.

2

Description

Average total score of severity and duration of primary dysmenorrhea

Timepoint

Calculation of the average score of severity and duration of dysmenorrhea at the beginning of the study (before the start of the intervention) and 1 and 2 months after the start of the intervention

Method of measurement

The mean total score of dysmenorrhea intensity by the visual pain scale (VAS) and the mean total score of pain duration by the scale COX menstrual scale will be investigated in the form of self-reporting by patients.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, oral oregano capsules will be used once a day from 7 days before menstruation to the first 3 days of menstruation.

Category

Treatment - Drugs

2

Description

Control group: In the control group, the placebo capsule will be used once a day from 7 days before menstruation to the first 3 days of menstruation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharestan Dormitory., Mashhad University of Medical Sciences Campus

Full name of responsible person

Fatemeh Erfanian

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Baharestan Dormitory., Mashhad University of Medical Sciences Campus., Bahonar St., Vakil Abad Blvd., Mashhad., Iran

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Sponsors / Funding sources

1

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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
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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