# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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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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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## Sponsors / Funding sources

**1**

**Sponsor**

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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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Mohaddeseh Borhaninasab
**Position**
Student
**Latest degree**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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