Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Lavandula Essence on the severity of premenstrual syndrome (PMS) in students.

Protocol summary

Study aim
Determining the effect of lavender essential oil on the severity of Premenstrual syndromesymptoms.

Design
"The intervention group will receive lavender essential oil inhalation for 11 days (7 days pre-menstrual and first 4 days of menstruation) over two months, with PMS symptoms recorded on a data form. The control group will receive almond oil inhalation using the same protocol."

Settings and conduct
Data will be collected using a demographic characteristics questionnaire, a provisional premenstrual syndrome (PMS) screening questionnaire, a daily symptom record form (PSST questionnaire), and the Beck Depression Inventory. Eligible participants will first complete the initial PMS screening questionnaire. Those who report at least 5 symptoms from the daily symptom record form during the week before menstruation through the fourth day of menstruation will be included in the study. These eligible participants will then complete the daily symptom record form for two consecutive months. After this two-month baseline period, participants will be randomly allocated to either the intervention or control group. The intervention group will receive aromatherapy via inhalation of 3 drops of lavender essential oil, twice daily, for 11 days (from 7 days before menstruation through the 4th day of menstruation). The control group will receive almond oil inhalation using the same protocol. The data analyst will remain blinded to group allocation throughout the study.

Participants/Inclusion and exclusion criteria
having regular menstruation (21-35 days), not taking hormonal and vitamin drugs.

Intervention groups
Aromatherapy will be performed twice a day with 3 drops of lavender essential oil from 7 days before menstruation to the fourth day of menstruation (14 days) by the participants themselves.

Main outcome variables
Severity of premenstrual syndrome symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230220057463N1**
Registration date: **2026-08-04, 1405/05/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-04, 1405/05/13**
Update count: **0**

Registration date
2026-08-04, 1405/05/13

Registrant information

Name
Arezoo Pirak

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 689 9447

Email address
pirak.arezoo@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-02, 1405/05/11

Expected recruitment end date
2027-03-02, 1405/12/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Lavandula Essence on the severity of premenstrual syndrome (PMS) in students.

Public title
The effect of Lavandula Essence on the severity of premenstrual syndrome (PMS) symptoms in students of Iranshahr University of Medical Sciences 1401

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having regular menstruation (21-35 days), not taking antidepressants in the last few months, not taking hormonal and vitamin drugs
Exclusion criteria:
Diagnosis of depression (with standard Beck questionnaire), the occurrence of events such as the death of relatives, divorce and other unfortunate events, occurrence of menstrual disorders during the study.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this way, according to the sample size, 80 cards were prepared, 40 cards with the letter A on it and 40 cards with the letter B written on it and placed in a container. All eligible students choose one of the cards, card A will be the intervention group and card B will be the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The groups are provided to the analyzer as A and B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iranshahr University of Medical Sciences

Street address
Baluch Blvd.- Roozbeh Psychiatric Hospital- Deputy Research and Technology

City
Iranshahr

Province
Sistan-va-Balouchestan

Postal code
9914786138

Approval date
2022-05-23, 1401/03/02

Ethics committee reference number
IR.IRSHUMS.REC.1401.003

Health conditions studied

1

Description of health condition studied
Premenstrual syndrome symptoms

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of premenstrual syndrome symptoms

Timepoint
7 days before menstruation and the first 4 days of menstruation

Method of measurement
Premenstrual Symptoms Questionnaire (PSST)

Secondary outcomes

empty

Intervention groups

1

Description
"Aromatherapy with lavender essential oil will be performed by the participants themselves, twice a day, with 3 drops of lavender essential oil, from 7 days before menstruation until the fourth day of menstruation (11 days total). In this study, 3 drops of lavender essential oil will be added to 200 mL of hot water; then, the participant's head will be covered with a towel while seated, and she will inhale the steam. This intervention will be carried out for 2 months.

Category
Rehabilitation

2

Description

Control group: In the control group, almond oil will be administered by the participants themselves twice daily, with 3 drops, starting 7 days before menstruation and continuing until the fourth day of menstruation (total of 11 days). In this study, 3 drops of almond oil will be added to 200 mL of hot water; then, the participant's head will be covered with a towel while seated, and she will inhale the steam. This placebo intervention will be carried out for 2 months in the control group

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranshahr University of Medical Sciences
Full name of responsible person
Arezoo pirak
Street address
Shahid Fath Moradi Highway - Faculty of Medicine
City
Iranshahar
Province
Sistan-va-Balouchestan
Postal code
9914786138
Phone
+98 54 3721 0483
Fax
+98 54 3721 3397
Email
pirak.arezoo@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranshahr University of Medical Sciences
Full name of responsible person
dr.farzaneh faraji
Street address
Baluch Blvd.- Roozbeh Psychiatric Hospital- Deputy Research and Technology
City
Iranshahar
Province
Sistan-va-Balouchestan
Postal code
9914786138
Phone
+98 54 3721 0483
Fax
+98 54 3721 3397
Email
pirak.arezoo@yahoo.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranshahr 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
Iranshahr University of Medical Sciences
Full name of responsible person
Arezoo pirak
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Shahid Fath Moradi Highway - Faculty of Medicine
City
Iranshahar
Province
Sistan-va-Balouchestan
Postal code
9914786138
Phone
+98 54 3721 0483
Email
pirak.arezoo@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranshahr University of Medical Sciences
Full name of responsible person
Arezoo pirak
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Shahid Fath Moradi Highway - Faculty of Medicine
City
Iranshahar
Province

Sistan-va-Balouchestan

Postal code

9914786138

Phone

+98 54 3721 0483

Email

pirak.arezoo@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iranshahr University of Medical Sciences

Full name of responsible person

Arezoo pirak

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Shahid Fath Moradi Highway - Faculty of Medicine

City

Iranshahar

Province

Sistan-va-Balouchestan

Postal code

9914786138

Phone

+98 54 3721 0483

Email

pirak.arezoo@yahoo.com

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

Yes - There is a plan to make this available

Title and more details about the data/document

Primary outcomes of the study: premenstrual syndrome (PMS) symptoms"

When the data will become available and for how long

After the results are published"

To whom data/document is available

Researchers worldwide

Under which criteria data/document could be used

If requested"

From where data/document is obtainable

the corresponding author

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

Applicants must submit a written request to the corresponding author after publication of the results. The request should include the applicant's name, institutional affiliation, purpose of access, and the specific data required. After approval by the research team, de-identified (coded) data will be sent via email. The entire process, from receipt of the request to data submission, is expected to take approximately 2 to 4 weeks.

Comments