

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparative study of the effect of Domask Rose essence and citrus aurantium on the severity of the symptoms of premenstrual syndrome in the students of Jahrom University of Medical Sciences

Protocol summary

Study aim

Determining the effect of Domask Rose and Citrus Aurantium essence on the severity of premenstrual syndrome symptoms in students of Jahrom University of Medical Sciences

Design

Clinical trial with two test groups and one control group, with parallel, double-blind, randomized groups, on 80 female students (all female students of operating room, anesthesia, and nursing).

Settings and conduct

This quasi-experimental study will be conducted on female students at Jahrom University of Medical Sciences. The Goldberg General Health Questionnaire (GHQ) will be completed to assess the mental health of the samples and the Premenstrual Symptoms Screening Questionnaire to determine the presence of PMS and its severity (for three consecutive menstrual cycles). Participants will be randomly divided into three groups. For the intervention, essential oil of rose and orange blossom in 15 cc bottles will be given to the first intervention group: domask rose essence, to the second intervention group: citrus aurantium essence, and to the third group, placebo sweet almond oil. In this way, during two menstrual cycles from 7 days before menstruation to the third day of menstruation, 5 drops of the contents of the desired bottle will be measured by the bottle's own dropper and complete the premenstrual symptoms screening questionnaire at the end of each menstrual cycle.

Participants/Inclusion and exclusion criteria

Willingness to participate in the study and completing the consent form, having premenstrual syndrome, not taking hormonal medications two months before the study.

Intervention groups

Intervention groups with Domask Rose and Citrus

Aurantium essence (one group 5 drops of Domask Rose essence and the other group 5 drops of Citrus Aurantium essence) and control group with placebo (5 drops of sweet Almond essence oil)

Main outcome variables

Symptoms of premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210502051161N3**

Registration date: **2025-05-22, 1404/03/01**

Registration timing: **prospective**

Last update: **2025-05-22, 1404/03/01**

Update count: **0**

Registration date

2025-05-22, 1404/03/01

Registrant information

Name

Hamidreza Nejati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5372 3872

Email address

hamidrezaa891425@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-02, 1404/07/10

Expected recruitment end date

2026-07-01, 1405/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of Domask Rose essence and citrus aurantium on the severity of the symptoms of premenstrual syndrome in the students of Jahrom University of Medical Sciences

Public title
Studying the effect of Domask Rose essence and citrus aurantium on premenstrual syndrome

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study
Completing the informed consent form
Having premenstrual syndrome based on self-report and questionnaire
Not taking hormonal medications for at least two months before the study
No use of any medication to reduce symptoms during menstruation or use of a specific medication such as painkillers by all participants
Not taking vitamin supplements one month before the start of the intervention
Absence of underlying physical and mental disorders based on the Goldberg General Health Scale
Having regular menstruation
Student dormitory resident
Exclusion criteria:
Unwillingness to continue participating in the study
The occurrence of stressful events during the study and the use of any other medication during the study
Changes in menstrual cycle intervals and duration based on criteria
Sensitivity to essences used in the study
Incomplete completion of questionnaires

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method in this study was simple random allocation, in which, based on the list of female students in the operating room, anesthesia, and nursing, using a random number table, the first and second selected numbers from the students class list were placed in the test group, and the third number was placed in the

control group in the same way. Allocation of samples in three groups continued until the number of samples was complete.

Blinding (investigator's opinion)
Double blinded

Blinding description
The students in the experimental and control groups will be placed in two separate locations. In the first experimental group, a bottle containing 15 cc of 40% Domask Rose essence, from Barij Essential Oil Company, Kashan, will be provided to the experimental group. In the second experimental group, a bottle containing 15 cc of Citrus Aurantium essence, from Barij Essential Oil Company, Kashan, will be provided to the experimental group. For the students in the control group, a bottle containing 15 cc of edible Sweet Almond oil will be provided to them. The bottles containing essence of Domask Rose, Citrus Aurantium, and edible sweet almond are the same shape and none will have a specification label and will be marked with labels A (Domask Rose essence), B (Citrus Aurantium essence), and C (Sweet Almond oil) to differentiate them. Then, all three groups will be given bottle A, bottle B, and the control group will be given bottle C, respectively. Sufficient information will be given to the groups on how to consume the contents of the bottles. In this way, during two menstrual cycles, from 7 days before menstruation to the third day of menstruation, they will measure and drink 5 drops of the contents of the desired bottle by the bottle's own mouthpiece. At the end of each menstrual cycle during the intervention period, they will be asked to complete a premenstrual symptoms screening questionnaire.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Jahrom University of Medical Sciences

Street address
Ostad Motahari Boulevard

City
Jahrom

Province
Fars

Postal code
7414846199

Approval date
2025-05-03, 1404/02/13

Ethics committee reference number

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

Screening for premenstrual symptoms

Timepoint

Before and after menstruation

Method of measurement

PSST questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aromatherapy is performed by individuals 1 week before menstruation until the third day of menstruation, twice a day for 5 minutes each time for 2 consecutive cycles, in a quiet place and in a stable and comfortable position, and they take 5 drops of the contents of the bottle with a dropper. For the first group, the dose of Domask rose essence used is 4% and for the second group, citrus aurantium essence is 0.5%.

Category

Treatment - Drugs

2

Description

Control group: Aromatherapy is performed by individuals 1 week before menstruation until the third day of menstruation, twice a day for 5 minutes each time for 2 consecutive cycles, in a quiet place and in a stable and comfortable position, and they take 5 drops of the contents of the bottle with a dropper. Sweet almond oil is used for this group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahrom University of Medical Sciences Dormitories

Full name of responsible person

Hamid Reza Nejati

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Ostad Motahari Street, Jahrom University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Amir Abdoli

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info@gmail.com

Web page address

<http://www.jums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Hamid Reza Nejati

Position

Surgical Technologist (Operating Room)

Latest degree

Master

Other areas of specialty/work

Operating Room

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Person responsible for scientific inquiries

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Position

Faculty instructor

Latest degree

Master

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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