Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of aromatherapy with rosa damascena, lavender and citrus aurantium essential oils on the severity of premenstrual syndrome symptoms in married women

Protocol summary

Study aim
Determining the effect of aromatherapy with essential oils of rosa damascena , lavender and citrus aurantium on the severity of symptoms of premenstrual syndrome in married women of Gonabad city - 1401

Design
The clinical trial has four parallel intervention and control groups, one blind with a sample size of 128 people who will be allocated in four groups by random stratified sampling.

Settings and conduct
After determining the students with premenstrual syndrome, the intervention groups dripped 10 drops of the delivered essential oil on a piece of cotton every day, 2 times a day, from 7 days before the start of menstruation until the fourth day of bleeding. They inhale from a distance of 10 cm from the nose for 5 minutes. The control group received odorless sweet almond oil like the intervention groups. This is done for two cycles and the PSST questionnaire is completed at the end of each cycle.

Participants/Inclusion and exclusion criteria
Willingness to participate in the study, age range 18-35 years, no medical and mental illnesses and disorders related to the reproductive system, menstrual cycles of 21-35 days with a duration of 4 - 8 days, suffering from moderate or severe premenstrual syndrome, not having a disorder in the olfactory system , lack of sensitivity to the essential oils used in the study.

Intervention groups
group 1: improvement of symptoms of premenstrual syndrome with 30% pure rosa damascena essential oil. group 2: Improvement of premenstrual syndrome symptoms with 30% pure lavender essential oil. group 3: Improvement of symptoms of premenstrual syndrome with pure 30% citrus aurantium essential oil. Control group: improvement of premenstrual syndrome symptoms with odorless sweet almond oil

Main outcome variables
Symptoms of premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230502058052N1**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **prospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date
2023-05-08, 1402/02/18

Registrant information

Name
Mahsa Rastegar

Name of organization / entity

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Iran (Islamic Republic of)

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+98 991 173 9624

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-04, 1402/03/14

Expected recruitment end date
2024-01-04, 1402/10/14

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of aromatherapy with rosa damascena, lavender and citrus aurantium essential oils on the severity of premenstrual syndrome symptoms in married women

Public title
Comparison of the effect of aromatherapy with rosa damascena, lavender and citrus aurantium essential oils on the severity of premenstrual syndrome symptoms
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Age range from 18 to 35 years Normal body mass index No smoking and drugs Absence of medical diseases and disorders related to the reproductive system based on the person's statements Not suffering from psychiatric diseases, anxiety disorders, depression and stress based on the person's statements Menstrual cycles of 21-35 days with a duration of 4-8 days Having moderate or severe premenstrual syndrome based on the PSST questionnaire Not using drugs or supplements effective on premenstrual syndrome from 2 months before the start of the study Not doing sports professionally No stressful event in the last 6 months No disorder in the olfactory system based on the person's statements
Exclusion criteria:
Unwillingness to continue cooperation Changes in the intervals of menstrual cycles (less than 21 days and more than 35 days) and the number of menstrual days (less than 4 days and more than 8 days) Taking drugs and supplements effective on premenstrual syndrome Allergy to the essential oils used in the study
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation of samples to each of the studied groups will be determined using 4 and 8 variable blocks and a computer program. Sealed sealed envelopes will be numbered sequentially and used to conceal the allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
Essential oils and placebo in identical bottles in terms of packaging shape and color; and are coded with A, B, C and D codes; And the study will be blinded in terms of research units.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Gonabad University of Medical Sciences
Street address
On the side of Asian Road, Gonabad University of Medical Sciences
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2022-12-30, 1401/10/09
Ethics committee reference number
IR.GMU.REC.1402.009

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
Symptoms of premenstrual syndrome
Timepoint
before the start of the intervention and during the intervention in two menstrual cycles
Method of measurement
Premenstrual syndrome symptoms screening questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: From 7 days before menstruation to the fourth day of menstrual bleeding, for two cycles, every day, 2 times a day, 10 drops of 30% rosa damascena essential oil were dripped on a piece of cotton and from a distance of 10 cm from the nose for 5 minutes with they inhale normally.
Category
Treatment - Drugs

2

Description
Intervention group: From 7 days before menstruation to the fourth day of menstrual bleeding, for two cycles, every day, 2 times a day, 10 drops of 30% lavender essential oil were dripped on a piece of cotton and from a distance of 10 cm from the nose for 5 minutes with they inhale normally.
Category
Treatment - Drugs

3

Description
Intervention group: From 7 days before menstruation to the fourth day of menstrual bleeding, for two cycles, every day, 2 times a day, 10 drops of 30% citrus aurantium essential oil were dripped on a piece of cotton and from a distance of 10 cm from the nose for 5 minutes with they inhale normally.
Category
Treatment - Drugs

4

Description
control group: From 7 days before menstruation to the fourth day of menstrual bleeding, for two cycles, every day, 2 times a day, drip 10 drops of odorless sweet almond oil on a piece of cotton and hold it from a distance of 10 cm from the nose for 5 minutes with they inhale normally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive health service centers of Gonabad city
Full name of responsible person
Mahsa Rastegar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
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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
Gonabad University of Medical Sciences
Proportion provided by this source
30
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
Gonabad University of Medical Sciences
Full name of responsible person

Mahsa Rastegar
Position
MSc student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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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
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
The participants are coded to increase access to them and their information, but at the time of publication, only the main result is published and the information of the participants is not published in any way.
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Access is open to the public
Under which criteria data/document could be used
If people have a request, without mentioning the coding of the information confidentially, without the personal information of the people, only the main and side results will be provided to the requester.
From where data/document is obtainable
E-mail
What processes are involved for a request to access data/document
First, the applicant sends a message to the e-mail and explains the reason for using the data, and within a week, information with conditions and restrictions will be sent to the applicant.
Comments