Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Aromatherapy with the Essential Oil of Geranium on Premenstrual Syndrome in Students of Gonabad University of Medical Sciences

Protocol summary

Study aim

The Effect of Aromatherapy with the Essential Oil of Granium on Premenstrual Syndrome in Students of Gonabad University of Medical Sciences

Design

This trial has two parallel groups, including the geranium essential oil group and the placebo group. The sample size estimated for this study is 60 people who will be divided randomly into two groups by simple random sampling.

Settings and conduct

This study will be conducted blindly in Gonabad University of Medical Sciences. In this study, researchers are unaware of the allocation of individuals to the geranium essential oils and placebo. Data collection is also based on a demographic information form, a screening tool for symptoms before Menstruation and General Health Questionnaire

Participants/Inclusion and exclusion criteria

Desire to participate in the plan, non-use of vitamin supplements, non-use of hormonal drugs at least 2 months ago, menstrual periods between 24 and 35 days, lack of underlying illness such as diabetes, thyroid disorders, or any mental disorder, business Scores higher than 20 from the screening questionnaire for premenstrual symptoms, gaining score less than 23 from the general health questionnaire, entry criteria Unwillingness to cooperate, stressful events during the cycle and intervention, changes in the menstrual cycle that reduce the period to less than 24 days or increase to over 35 days, changes in the menstrual cycle leading to Reduce the number of bleeding days to less than 3 days or increase it to more than 7 days. Occurrence such as marriage, surgery, at least 3 months before the start of the study, sensitivity to the essential oil of the herb, exit criteria

Intervention groups

In the intervention group, the essential oil of the geranium plant with a concentration of 0.5% will be used. In the control group, the drug (sweet almond oil) will be used

Main outcome variables

of Granium on Premenstrual Syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181029041495N2**
Registration date: **2019-03-18, 1397/12/27**
Registration timing: **retrospective**

Last update: **2019-03-18, 1397/12/27**
Update count: **0**

Registration date

2019-03-18, 1397/12/27

Registrant information

Name

Mohsen Aliakbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5733 2028

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-08, 1397/07/16

Expected recruitment end date

2019-01-14, 1397/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aromatherapy with the Essential Oil of Geranium on Premenstrual Syndrome in Students of Gonabad University of Medical Sciences

Public title

The effect of geranium essential oil on premenstrual syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the plan Not using vitamin supplements No use of hormonal medications at least 2 months ago The length of the menstrual period is between 24 and 35 days Lack of underlying disease, such as diabetes, thyroid gland disorders, or any mental disorder Earning score above 20 from the screening questionnaire for symptoms of premenstrual syndrome Earn less than 23 points from the General Health Questionnaire

Exclusion criteria:

Unwillingness to cooperate Occurrence of stressful events during the cycle and intervention Changes in the menstrual cycle that result in a decrease in the duration of the period to less than 24 days or increase to more than 35 days. Changes in the menstrual cycle that lead to a reduction in the number of bleeding days to less than 3 days or an increase of more than 7 days. Occurrence such as marriage, surgery, at least 3 months before the start of the study Sensitivity to essential oil of geranium

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the method of permutation blocks (30 blocks, dual) was used. For this purpose, the letter A represents the group of geranium and letter B, representing the control group, and there were two possible cases of AB and BA. Then the contract is closed if, in the random numbers table, the number of pairs is replaced by AB, and if the number is the case, the BA substitution of the patients in the groups is performed. In this case, if in the random numbers table, the number of paired numbers entering the study was placed in the geranium group and the next person was placed in the control group. In the random numbers table, if the odd number came from the BA permutation block, that is, the first patient in the control group and the second patient in the geranium group. All numbers were randomly selected using random numbers. It should be noted that the direction and direction of movement in the random numbers table were determined in advance. This work continued until the determination of 30 double blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the blinding of samples and researchers, the essential oils are presented in a dish of the same color and shape. For intervention, twice a day, 10 drops of essential oil are poured onto cotton and pinched with a pin at a distance of 30 cm from the nose, and the subject will breathe in for a period of 5 minutes with ordinary breathing.

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

Gonabad University of Medical Sciences,Asian Roads,Gonabad,Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-02-12, 1397/11/23

Ethics committee reference number

IR.GMU.REC.1397.099

Health conditions studied

1

Description of health condition studied

Granium on Premenstrual Syndrome

ICD-10 code

N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Granium on Premenstrual Syndrome
Timepoint
Before and after two consecutive menstrual cycles
Method of measurement
Demographic data form, Premenstrual symptoms screening tool and General Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In order to interfere with the essential oil of the geranium herb with a concentration of 0.05% from Barij Essen. Each person will be given 5 ml of essential oil for one month. Twice a day, 10 drops of essential oil will be poured on cotton and pinched with a pin at a distance of 30 cm from the nose, and will inhale the fragrances every 5 minutes with ordinary breathing.
Category
Prevention

2

Description
Control group: In order to interfere with the sweet odorless sweet almond oil from Barís Essence, the company bought. Each person will be given 5 ml of almond oil for one month. Twice a day, 10 drops of oil will be poured on cotton and pinched with a pin at a distance of 30 cm from the nose, and will breathe the personally breathable scent every 5 minutes.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fajr University of Medical Sciences Gonabad University of Medical Sciences
Full name of responsible person
Fatemeh Gholamian
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Sajjadi
Street address
Gonabad University of Medical Sciences,Asian Roads,Gonabad, Iran
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Sajjadi.sal@gmail.com
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
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
Gonabad University of Medical Sciences
Full name of responsible person
Fatemeh Ggholamian
Position
student
Latest degree
Bachelor
Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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Mohsen Aliakbari

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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