Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 2026

"Investigating the Effects of Pelargonium graveolens Soft Capsules on the Severity of Primary Dysmenorrhea in Students of Islamic Azad University, Shahrekord: A Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of geranium capsule on the severity of primary dysmenorrhea in students of Shahrekord Azad University

Design
A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 72 people.

Settings and conduct
Students of Shahrekord Azad University with primary dysmenorrhea and triple blinding will be performed, with blinding of participants, the research team, and individuals involved in data analysis.

Participants/Inclusion and exclusion criteria
Single female students aged 18 to 25 with regular menstruation and moderate to severe primary dysmenorrhea according to the visual analog scale. Compliance with the study protocol, occurrence of underlying, physical or psychological diseases, and occurrence of new serious complications in menstruation, occurrence of sensitivity or side effects due to interventions. Consumption of any herbal tea, any chemical or hormonal medication, and known physical or psychological disease, addiction to cigarettes, alcohol, and similar things, receiving complementary treatment.

Intervention groups
The intervention group receives 50 mg of scented geranium capsules standardized based on 15 to 22 mg of citronellol twice a day after meals for 2 consecutive cycles. The control group also receives a placebo capsule containing base oil . Participants in both groups are given 250 mg of mefenamic acid capsules and are instructed to use mefenamic acid capsules every 8 hours if the pain is not controlled by taking geranium capsules and placebo and to record the number of capsules consumed in the daily checklist.

Main outcome variables
The severity, quality, and duration of primary dysmenorrhea and the amount of menstrual bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250803066739N1**
Registration date: **2025-09-19, 1404/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-19, 1404/06/28**
Update count: **0**

Registration date
2025-09-19, 1404/06/28

Registrant information

Name
Azam Motamedi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 38 3242 7668

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-06, 1404/06/15

Expected recruitment end date
2025-11-21, 1404/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
"Investigating the Effects of Pelargonium graveolens Soft Capsules on the Severity of Primary Dysmenorrhea in Students of Islamic Azad University, Shahrekord: A Randomized Clinical Trial

Public title
The effect of Pelargonium graveolens Capsules on the severity of menstrual pain in female students.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having moderate to severe primary dysmenorrhea (score equal to or greater than 4 on the visual analog scale), being single, being students between 18 and 25 years old (the age group with the highest incidence of PD and the most severe clinical manifestations), having a regular menstrual cycle of 21 to 35 days, and willingness to participate in the study.

Exclusion criteria:
Medical students at Shahrekord Azad University with primary dysmenorrhea, a history of regular exercise, consumption of any herbal tea, any known physical disease, any known psychological disease, consumption of any medication (chemical or herbal and hormonal), addiction to cigarettes, alcohol and similar things, allergy to medicinal herbs.

Age
From **18 years** old to **25 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Blinding will be performed in a triple-blind manner, with blinding of participants, the research team, and individuals involved in data analysis. The geranium and placebo capsules will be identically prepared by Barich Essential Oils Company and will be labeled A and B. Due to the blinding of the study, the contents of A and B will remain unknown to the research team, the study samples, and the data analyst until the study is completed, and they will not know the nature of the capsules. A limited random allocation method will be used for randomization. For this purpose, 36 cards labeled A and 36 cards labeled B will be mixed together and placed in an envelope, and one card will be drawn at random for each research unit. The label of the drawn card will indicate the treatment intervention group and will be recorded.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Blinding will be performed in a triple-blind manner, with blinding of participants, the research team, and individuals involved in data analysis. The geranium and placebo capsules will be identically prepared by Barich Essential Oils Company and will be labeled A and B. Due to the blinding of the study, the contents of A and B will remain unknown to the research team, the study samples, and the data analyst until the study is completed, and they will not know the nature of the capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Research and Technology Deputy, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord, Iran

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Approval date
2025-06-29, 1404/04/08

Ethics committee reference number
IR.SKUMS.REC.1404.049

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhea

ICD-10 code
N94.4Prima

ICD-10 code description
Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description
Percentage of students with severe primary dysmenorrhea in the two groups
Timepoint
Before the start of the intervention, one month after the end of the intervention, and two months after the end of the intervention
Method of measurement
Visual Analogue Pain Scale

2

Description
Quality of primary dysmenorrhea in two groups
Timepoint
Before the start of the intervention, one month after the end of the intervention, and two months after the end of the intervention
Method of measurement
McGill Pain Questionnaire Short Form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group received 50 mg soft capsules of fragrant geranium essential oil standardized based on 15 to 22 mg of citronellol (manufactured by Barich Essential Oils) twice a day after meals for 2 consecutive cycles (76). The control group also received placebo capsules containing base oil (in the same shape and packaging as the fragrant geranium soft capsules) and ordered from Barich Essential Oils. Participants in both groups were given 250 mg capsules of mefenamic acid and were instructed to use mefenamic acid capsules every 8 hours if pain was not controlled by geranium and placebo capsules and to record the number of capsules consumed in a daily checklist.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord Azad University
Full name of responsible person
Azam Motamedi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Faranak Safdari

Position
Assistant Professor, head of the Midwifery Department
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available