Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of aromatherapy massage using Rosa damascena oil on the severity of pain caused by primary dysmenorrhea in students

Protocol summary

Study aim

The effectiveness of aromatherapy massage using Rosa damascena oil on the severity of pain caused by primary dysmenorrhea in students

Design

A phase 3, randomized, controlled clinical trial with two parallel groups will be conducted on 104 individuals with primary dysmenorrhea. Randomized blocks of 4 will be created using a random number table.

Settings and conduct

Female Pharmacy and Dentistry students of Zanjan University of Medical Sciences will massage one mg of Rosa damascena oil on the skin of the suprapubic area three times a day for 10 minutes for three consecutive menstrual cycles. This treatment will begin the day before menstruation and continue for three days after. We will not be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Students aged 18 to 35 years, regular menstruation, primary dysmenorrhea level 1 to 2 according to the Multidimensional Verbal Scoring System, usual sense of smell, and ability to smell fragrances. Exclusion criteria: Allergy to Rosa damascena, suspected pregnancy, use of hormonal contraceptives, use of analgesics other than mefenamic acid, abnormal uterine bleeding, and secondary dysmenorrhea.

Intervention groups

Control group: Routine treatment including taking 500 mg mefenamic acid capsules every 6 hours for the first three days of menstruation Intervention group: Massage one mg of Rosa damascena oil, three times a day for 10 minutes on the skin of the suprapubic area two days before the onset of menstruation to three days after it

Main outcome variables

Menstrual pain intensity; menstrual pain duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250226064865N1**
Registration date: **2025-03-15, 1403/12/25**
Registration timing: **prospective**

Last update: **2025-03-15, 1403/12/25**
Update count: **0**

Registration date

2025-03-15, 1403/12/25

Registrant information

Name

Samineh Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 3635

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jafari_s@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-04, 1404/01/15

Expected recruitment end date

2025-12-06, 1404/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of aromatherapy massage using Rosa damascena oil on the severity of pain caused by primary dysmenorrhea in students

Public title
The effectiveness of aromatherapy massage using Rosa damascena oil on the severity of pain caused by primary dysmenorrhea in students

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Regular menstruation Primary dysmenorrhea, grade 1 to 2, based on the Verbal Multidimensional Scoring System Having a normal sense of smell and ability to smell perfumes Willingness to participate in the study

Exclusion criteria:
Allergy to Rosa damascena Suspected pregnancy Use of hormonal contraceptives The use of other pain relievers except mefenamic acid History of abnormal uterine bleeding Having chronic pelvic inflammatory disease Having systemic diseases secondary dysmenorrhea History of pelvic or abdominal surgery Having an ovarian cyst Congenital anomalies of the genital tract

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible individuals will be selected by convenience sampling and then allocated to the intervention and control groups using a 4-block random sampling method. For this purpose, the 26 blocks of four will be selected using a random number table, resulting in a sample size of 52 individuals per group. Blocking will be performed by a person not involved in the sampling.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Blvd. of Ostad Saboti, Zanjan University of Medical Sciences,Zanjan

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Zanjan

Province
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Postal code
4513956184

Approval date
2025-01-20, 1403/11/01

Ethics committee reference number
IR.ZUMS.REC.1403.284

Health conditions studied

1

Description of health condition studied
Primary Dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
The severity of menstrual pain

Timepoint
In three time periods: 8-13, 13-18 and 18-24 per day for three consecutive cycles

Method of measurement
Visual analog scale

2

Description
Duration of menstrual pain

Timepoint
In three time periods: 8-13, 13-18 and 18-24 per day for three consecutive cycles

Method of measurement
Total number of hours of pain per cycle

Secondary outcomes

1

Description
The need to use drug therapy to reduce pain

Timepoint
The end of each menstrual cycle for three consecutive months

Method of measurement
The number of capsules of mefenamic acid consumed

Intervention groups

1

Description
The intervention group will massage one cc of Rosa damascena Barij essential oil topically onto the pubic for 10 minutes, three times a day, starting two days before the start of menstruation and ending three days after. The massage will be done with the palm of one hand in a back-and-forth motion without additional pressure.
Category
Treatment - Drugs

2

Description
The control group will receive routine treatment, which includes 500 mg of mefenamic acid capsules from the onset of menstrual symptoms until 3 days after.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Pharmacy, Zanjan University of Medical Sciences
Full name of responsible person
Samineh Jafari
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Professor Sobuti Boulevard ,Next to Ayatollah Mousavi Hospital, Faculty of Pharmacy,Zanjan , Iran
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Fax
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Email
research@zums.ac.ir
Web page address
https://research.zums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Elaheh Rahmati
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
Zanjan University of Medical Sciences

Full name of responsible person
Samineh Jafari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacognosy

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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
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

Title and more details about the data/document
The entire data cannot be shared after de-identifying individuals, but some of the information related to the main outcome can be shared.

When the data will become available and for how long
One year after the results were published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
In order to conduct scientific studies under the conditions of obtaining permission and observing the principles of research ethics

From where data/document is obtainable
Person responsible for scientific accountability of the

study

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

One year after the article was published

Comments