Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of oral use of Mentha Longifolia capsule on the symptoms of premenstrual syndrome and primary dysmenorrhea

Protocol summary

Study aim
Determining the effect of mint oral capsule on premenstrual syndrome and primary dysmenorrhea

Design
Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 3 on 64 patients. PASS software will be used for randomization.

Settings and conduct
Sampling will be done in the dormitories of Mashhad University of Medical Sciences. Both intervention and control groups are monitored for 2 months for definitive diagnosis of dysmenorrhea and PMS. Then, 7 days before the onset of menstruation until the first 3 days of menstruation, they will receive one 750 mg capsule daily for two cycles, which before and three hours after taking the drug, the pain intensity using the pain visual scale and Pain duration will be recorded using the Cox scale. Symptoms of PMS will be measured by the premenstrual calendar form. the symptoms of PMS and the severity and duration of dysmenorrhea before, one and two months after the intervention will be compared with the control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being Iranian and single, living in the dormitories of Mashhad University of Medical Sciences, regular menstruation, age 18-35 years, having PMS and dysmenorrhea at the same time, no specific disease, no medication, no Allergy to mint. Withdrawal conditions: Discontinuation or irregular use of medication, BMI greater than 30, Depression, Severe stress and anxiety, Experience of an unfortunate or stressful accident while studying

Intervention groups
The intervention group was treated with mint capsule, each capsule containing 750 mg of mint extract, 1 dose daily from 7 days before menstruation to the first three days of menstruation for 2 months. Control group during this period will receive the placebo capsule at the same conditions.

Main outcome variables
The mean total score of PMS symptoms؛ the severity and duration of dysmenorrhea.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210630051749N1**
Registration date: **2021-07-05, 1400/04/14**
Registration timing: **prospective**

Last update: **2021-07-05, 1400/04/14**
Update count: **0**
Registration date
2021-07-05, 1400/04/14

Registrant information
Name
Mahsa Houra
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3859 1511
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-07-11, 1400/04/20
Expected recruitment end date
2022-01-10, 1400/10/20
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral use of Mentha Longifolia capsule on the symptoms of premenstrual syndrome and primary dysmenorrhea

Public title

The effect of oral use of Mentha Longifolia capsule on the symptoms of premenstrual and the severity and duration of menstrual pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be Iranian and single. Be a resident of the dormitories of Mashhad University of Medical Sciences. Have regular menstruation Have premenstrual syndrome and primary dysmenorrhea at the same time. Be 18-35 years old. No medication No allergies to mint No alcohol or drugs or tobacco No diet No disease

Exclusion criteria:

Discontinuation of medication or irregular use of medication (not taking medication twice or more) Have a BMI of more than 30. Be a professional athlete. Suffer from depression, stress and anxiety . Experience an unfortunate or stressful event while studying. Has used traditional medicine methods to reduce symptoms and improve pain. Married while studying.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The research units are easily selected and divided into two groups receiving mint capsules and placebo by random allocation of block type and using PASS software. The drug concealment method is coded in the same package in terms of shape and design.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Researchers, participants, and the Data Safety and Supervision Committee will keep blind in this study. They will have no information about the attribution of individuals to groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Khorasan Razavi, Mashhad, Daneshgah St., Ph.D. Crossroads, Ibn Sina St., School of Nursing and Midwifery

City

مشهد

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2021-06-30, 1400/04/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.029

Health conditions studied

1

Description of health condition studied

primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary Dysmenorrhea

2

Description of health condition studied

Premenstrual syndrome

ICD-10 code

R10.3

ICD-10 code description

Pain localized to other parts of lower abdomen

Primary outcomes

1

Description

Mean score of total premenstrual syndrome symptoms, severity and duration of dysmenorrhea

Timepoint

Mean score of total symptoms of premenstrual

syndrome, severity and duration of dysmenorrhea at the beginning of the study (before the intervention) and 1 and 2 months after the intervention

Method of measurement

The mean total score of premenstrual syndrome symptoms will be assessed by COPE premenstrual events calendar form and the severity and duration of dysmenorrhea in the first and second months of the treatment cycle, by visual pain scale and COX scale and by patients' self-report.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, mint oral capsule will be used once a day from 7 days before the start of menstruation until the first 3 days of menstruation.

Category

Treatment - Drugs

2

Description

Control group: In the control group, mint oral capsule will be used once a day from 7 days before the start of menstruation until the first 3 days of menstruation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University Medical Sciences_Baharestan enghelab Dormitory

Full name of responsible person

Zolfaghar Yaghoubi

Street address

Mashhad, Vakilabad Boulevard, Bahonar St., Medical Sciences Dormitory

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YaghoubiFZ1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Razavi Khorasan Province, Mashhad, Daneshgah Avenue

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Samira Ebrahimzadehzagami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person
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Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
Mahsa Houra

Position
Master student of midwifery

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Bachelor

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Midwifery

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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