

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effect of rosemary capsule and mefenamic acid on the quality of life of early painful menstruation students

Protocol summary

Study aim

Comparison of the effect of rosemary capsule and mefenamic acid on the quality of life of primary dysmenorrhea students

Design

Clinical trials with control group, parallel groups, Double blind, Sample size: 90 people, Phase trials: 3

Settings and conduct

The study was double-blind in groups A and B at Mashhad Islamic Azad University School of Medicine

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iran and is unmarried; The age of research units at least 18 years; have regular menstrual cycle; Pain a few hours before or at the same time occur with menstrual bleeding; Menstrual pain can take 3 days or less; The mean pain score on the visual analogue pain 40 to 70 mm; The past six months have severe psychological stress. Exclusion criteria: The use of oral contraceptives or other steroid hormones; history of allergic reaction to mefenamic acid is consumed and rosemary: consume supplements.

Intervention groups

Control group: treated with mefenamic acid 250 mg every 8 hours for 2 menstrual cycle in the first three days of the menstrual cycle Intervention group: Rosemary If not treated with capsules for 2 menstrual cycle every 8 hours for the first three days of the menstrual cycle.

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160622028586N2**

Registration date: **2018-06-07, 1397/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-07, 1397/03/17**

Update count: **0**

Registration date

2018-06-07, 1397/03/17

Registrant information

Name

Fahimeh Tahoonian Golkhatmy

Name of organization / entity

School of Nursing and Midwifery, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3846 1567

Email address

tahounehf931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-10, 1397/02/20

Expected recruitment end date

2018-09-11, 1397/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of rosemary capsule and mefenamic acid on the quality of life of early painful menstruation students

Public title

Comparison of rosemary capsule and mefenamic acid on the quality of life of primary painful menstruation students

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Iran and is unmarried The age of research units at least 18 years Have regular menstrual cycle Pain a few hours before or at the same time occur with menstrual bleeding Menstrual pain can take 3 days or less The mean pain score on the visual analogue pain 40 to 70 mm The past six months have severe psychological stress Is not known medical illness! Do not use a particular drug Do not use a particular drug Is not special diet such as weight loss diet, obesity, vegetarian and water treatment Do not use Tobacco or alcohol! Do not regular exercise Do not regular exercise; Do not have severe bleeding menstrual.

Exclusion criteria:

The use of oral contraceptives or other steroid hormones History of allergic reaction to mefenamic acid is consumed and rosemary Consume supplements

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment by PASS software

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant, researcher, and evaluator of the outcomes dont know of the drug used.

Placebo

Not 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

Mashhad University of Medical Sciences, University Ave

City

mashhad

Province

Razavi Khorasan

Postal code

91735951

Approval date

2018-05-09, 1397/02/19

Ethics committee reference number

IR.MUMS.REC.1397.036

Health conditions studied

1

Description of health condition studied

Quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of life

Timepoint

30 days

Method of measurement

Quality of Life Questionnaire (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: treated with Mefenamic Acid 250 mg every 8 hours for 2 menstrual cycle in the first three days of the menstrual cycle

Category

Treatment - Drugs

2

Description

Intervention group: Rosemary If not treated with capsules for 2 menstrual cycle every 8 hours for the first three days of the menstrual cycle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Islamic Azad University School of Medicine

Full name of responsible person

Fahimeh Tahoonian Gholkhatmy

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No. Imam Khomeini 14, Bazarche Sarab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Fahimeh Tahoonian Gholkhatmy

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Person responsible for updating data

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Position

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Latest degree

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Midwifery

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

data can shared

When the data will become available and for how long

After publishing articles

To whom data/document is available

researchers

Under which criteria data/document could be used

People who want to investigate.

From where data/document is obtainable

Send the person responsible for the email.

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

If agreed by the project co-workers

Comments