

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of rosemary and Mefenamic Acid Capsules of amount of menstrual bleeding and Primary dysmenorrhea

Protocol summary

Summary

1. Objective: Comparison of mean pain intensity and amount of menstrual bleeding before and after intervention in clients that complains of primary dysmenorrhea with taking Rosemary and Mefenamic acid capsules. 2. Design: This study was a double-blind clinical trial conducting. 3. Setting and conduct: Research units with Inclusion criteria easy sampling was after completing the list of questionnaire and obtaining informed consent of subjects enrolled in research and they will be asked the most severe pain at the end of each day (3 days) and the amount of menstrual cycle (within 7 days of menstrual bleeding) specified in the list of first and second cycle and then delivered to researcher. Research units were randomly assigned to groups based on the software PASS Rosemary allocated into Rosemary and Mefenamic acid groups and had given Rosemary and Mefenamic acid capsules that their nature is identified with the letters A and B will be marked only for pharmacist consultant to be delivered to research units. They use in first three days first and second cycle intervention and complete the questionnaire and to submit researcher. 4. Participants including major eligibility criteria: students of Islamic Azad University Mashhad University of Medical Sciences with primary dysmenorrhea who have: Inclusion criteria: regular menstrual cycles; A few hours before or concurrent pain with the of menstrual bleeding; have 3 days or less menstrual pain; The mean pain score on the visual analogue pain is 40 to 70 mm; Don't have known medical disease; Not to use a particular drug; Don't have severe bleeding. Exclusion criteria: the use of oral contraceptives or other steroid hormones; A history of allergic reaction to the use of rosemary and Mefenamic acid is present. 5. Intervention: Control group: treated with mefenamic acid 250 mg every 8 hours for two menstrual cycles in the first three days of the menstrual cycle. Intervention group: treatment with rosemary capsules (containing 1 g) of alcoholic extract of rosemary

two menstrual cycles every 8 hours for the first three days of the menstrual cycle. 6. Main outcome measures (variables): Primary dysmenorrhea pain, the amount of menstrual bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062228586N1**

Registration date: **2016-09-28, 1395/07/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-28, 1395/07/07

Registrant information

Name

Fahimeh Tahoounian Golkhatmy

Name of organization / entity

School of Nursing and Midwifery, Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-11-20, 1395/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Comparing the effects of rosemary and Mefenamic Acid Capsules of amount of menstrual bleeding and Primary dysmenorrhea
Public title
Rosemary effect on the amount of menstrual bleeding and Primary dysmenorrhea
Purpose
Treatment
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! 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 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
Gender
Female
Phase
3
Groups that have been masked
No information
Sample size
Target sample size: 90
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences Ethics Committee

Street address

Mashhad University of Medical Sciences, University Ave

City

Mashhad

Postal code

Approval date

2016-06-23, 1395/04/03

Ethics committee reference number

IR.MUMS.REC.1395.162

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

Primary dysmenorrhea pain severity

Timepoint

3 the first day of menstrual bleeding

Method of measurement

According to the Visual Analogue Scale (vas)

Secondary outcomes

1

Description

The amount of menstrual bleeding

Timepoint

Menstrual bleeding period (7 days to 10 days menstrual cycle)

Method of measurement

Hygam chart

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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Bazarche Sarab, No. Imam Khomeini 14

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

University Ave

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Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Mashhad University

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Full name of responsible person

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Position

Master of Midwifery student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty