Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 dysmenorrheal 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 ofquestionnaire 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; have3 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 Tahoonian Golkhatmy

Name of organization / entity

School of Nursing and Midwifery, Mashhad University of Medical Sciences

Country

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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
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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