

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing effect of bromelain and Mefenamic acid on primary dysmenorrhea pain and bleeding

Protocol summary

Summary

Objective: Comparison of pain and menstrual bleeding before and after intervention in clients that complains of primary dysmenorrhea with taking and Mefenamic acid capsules. **Design:** This study was a single-blind clinical trial conducting. **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 (The first three 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 Lottery allocated into bromelain and Mefenamic acid groups and had given bromelain and Mefenamic acid capsules that their nature is identified with the letters A and B delivered to research units and they will be asked to take the drugs in the first three days of the first and second cycles of intervention and complete the questionnaire and to submit researcher. **The study population:** 90 students living in dorms of velayat university of iranshahr with primary dysmenorrhea who have Inclusion criteria: having regular menstrual cycles; age range between 18-25 years; having menstrual periods of moderate to severe primary dysmenorrhea grade based on Wong-Baker scale picture of pain. **Exclusion criteria:** Having a history of uterine problems; having hormone therapy at least three months before or during the course; Medical disease. **Intervention:** The first intervention group: treated with bromelain 250 mg for two menstrual cycles every 6 hours for the first three days of the menstrual cycle. The second intervention group: treated with mefenamic acid 250 mg every 6 hours for two menstrual cycles in the first three days of the menstrual cycle. **Main outcome measures :** Primary dysmenorrhea pain, menstrual bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112131000N1**

Registration date: **2016-12-26, 1395/10/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-26, 1395/10/06

Registrant information

Name

Bibi Maryam Mirlashari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 3007

Email address

mirlm931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-12-06, 1395/09/16

Expected recruitment end date

2017-04-05, 1396/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of bromelain and Mefenamic acid on primary dysmenorrhea pain and bleeding

Public title

Bromelan's effect on the pain and bleeding of Primary dysmenorrhea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian and being single; age range between 18-25 years; education in fields except medical science; female students studying in Iranshahr velayat university dormitories; Having the characteristics of primary dysmenorrhea (Pain period with the start a few hours before or Simultaneous of menstrual bleeding and continued for up to 72 hours); having regular menstrual periods; having menstrual periods of moderate to severe primary dysmenorrhea grade based on Wong-Baker scale picture of pain. .Exclusion criteria: Having a history of uterine problems; Continually taking certain drugs; having hormone therapy at least three months before or during the course; A special diet, such as vegetarian diets and water; Psychological stress during the last six months; professional athlete; Having coagulation disorders; High blood pressure; Liver and kidney disorders; Medical disease.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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

Street address

University Avenue, Building Qureshi

City

Mashhad

Postal code

13944-91388

Approval date

2016-07-16, 1395/04/26

Ethics committee reference number

IR.MUMUS.REC.1395.230

Health conditions studied**1****Description of health condition studied**

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes**1****Description**

Pain and bleeding

Timepoint

Two cycles before the intervention

Method of measurement

the first and second cycles of the intervention

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group: treated with Bromelain 250 mg every 6 hours for 2 menstrual cycle in the first three days of the menstrual cycle

Category

Treatment - Drugs

2**Description**

The second intervention group: treated with mefenamic acid 250 mg every 6 hours for 2 menstrual cycle in the first three days of the menstrual cycle

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Velayat University of Iranshahr

Full name of responsible person

Bibi Maryam Mirlashari. Graduate Student Midwives

Street address

5 km highway martyr Moradi,Velayat University

City

Iranshahr

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen tafaghodiy

Street addressUniversity Avenue. Central Organization of Mashhad
University of Medical Sciences**City**

Mashhad

Grant name**Grant code / Reference number**

00

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

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**

Mashhad University of Medical Sciences

Full name of responsible person

Bibi Maryam Mirlashari

Position

Graduate Student Midwives

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Abedian

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Master of Midwifery

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Position

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Web page address**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