Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)
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+98 51 3841 3007
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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 address
University 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
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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