Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Mint efficacy on primary dysmenorrhea in comparison with Mefnamic Acid

Protocol summary

Summary

Objective: Determining the effect of peppermint capsule in comparison with mefenamic acid on primary dysmenorrheal. Design: Double blind crossover randomized clinical trial. Inclusion Criteria: a) Primary dysmenorrhea; b) Single; c) 18-25 years old. Exclusion criteria: a) Contraindication of mint including obstruction of common bile duct, allergy, cholecystitis, chronic liver disease, and gastroesophageal reflux, b) contraindication of mefenamic acid including: allergy, gastritis, gastric ulcer, chronic renal failure, chronic liver disease, anemia, asthma, diabetes mellitus. Sample size: 432. Interventions: Group1: Peppermint oil capsule (commercial name:colpermin) TDS for 3 days. Group 2: Mefenamic acid capsule (commercial name: Ponstan manufactured by Razak Co.) 250 mg TDS for 3 days. Control group: Placebo capsule. Outcomes: a) symptoms, b) the duration pain, c) the severity of pain, d) bleeding, e) nausea, f) vomiting, g) diarrhea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011205206N1**
Registration date: **2011-02-06, 1389/11/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-02-06, 1389/11/17

Registrant information

Name

Hurieh Rezvani asl

Name of organization / entity

Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2011-02-19, 1389/11/30

Expected recruitment end date

2012-02-19, 1390/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Mint efficacy on primary dysmenorrhea in comparison with Mefnamic Acid

Public title

Effect of Mint and Mefnamic Acid on Menstrual Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: a) Primary dysmenorrhea; b) Single; c) 18-25 years old. Exclusion criteria: a) Contraindication of mint including obstruction of common bile duct, allergy, cholecystitis, chronic liver disease, and gastroesophageal reflux, b) contraindication of mefenamic acid including: allergy, gastritis, gastric ulcer, chronic renal failure, chronic liver disease, anemia, asthma, diabetes mellitus.

Age

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

Gender

Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **432**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamadan University of Medical Sciences
Street address
In front of Mardom Park Mahdieh St.
City
Hamadan
Postal code
518/65178
Approval date
2010-12-06, 1389/09/15
Ethics committee reference number
137435/9/35/16/پ

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
Duration of Dysmenorrhea
Timepoint
After taking
Method of measurement
Standard questionnaire (COX)

2

Description
Severity of Menstrual pain
Timepoint
After taking
Method of measurement
Standard questionnaire of pain violence(vas)

3

Description
Amount of menstrual bleeding
Timepoint
End of menstrual periods
Method of measurement
Standard questionnaire of Hylgam menstrual bleeding

4

Description
Nausea
Timepoint
End of menstrual periods
Method of measurement
Questionnaire

5

Description
Vomiting
Timepoint
End of menstrual periods
Method of measurement
Questionnaire

6

Description
Diarrhea
Timepoint
End of menstrual periods
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Side effects
Timepoint
After taking
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group1: Peppermint oil capsule (commercial name:colpermin) TDS for 3 days
Category
Treatment - Drugs

2

Description
Intervention group 2: Mefenamic acid capsule (commercial name: Ponstan) manufactured by Razak Co. 250 mg TDS for 3 days
Category
Treatment - Drugs

3

Description
Control group: Placebo capsule containing sugar
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitories of Hamadan University of Medical Sciences & Hamadan University
Full name of responsible person
Hurieh Rezvani asl
Street address
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Dr Ghaleiha Ali
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In front of Mardom Park Mahdieh St.
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan 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