

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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 dysmenorrhea. 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 of 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

Country

Iran (Islamic Republic of)

Phone

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Email address

zahra.masoumi@umsha.ac.ir

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 Mahdiah 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

Street address

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

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Jalal Poorolajal

Position

PhD of Epidemiology

Other areas of specialty/work

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Full name of responsible person

Hurieh Rezvani Asl

Position

Bachelor of Midwifery

Other areas of specialty/work

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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