Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the efficacy of herbal extrats (Fenellin & Vitagnus) and Mefenamic acid in the treatment of primary dysmenorrhea and menstrual bleeding

Protocol summary

Summary

The aim of this study is to evaluate the treatment efficacy of different treatment modalities in primary dysmenorehoea. This study was conducted in Hamadan on female students of Hamadan University of Medical Sciences during 1388-1389 educational years. Female student with primary dysmenorreha were included in the study and the exclusion criteria were: 1-Any systemic disease such as liver, kidney, thyroid and coagulation disease; 2- Hypersensitivity to drug; 3-Use of analgesic drugs during the study; 4-Use of OCP or IUD. Study participants will be divided in 4 groups. Group 1 will receive Fenellin, 30 drops every 4 hours beginning one day before the start of the cycle until the third day; Group 2 will receive Vitagnus 40 once a day in the morning beginning one day before the start of the cycle until the third day; Group 3 will receive Mefenamic acid 250 mg capsules every 4 hours beginning one day before the start of the cycle until the third day; Group 4 will receive Placebo, 30 drops every 4 hours beginning one day before the start of the cycle until the third day. Pain intensity and the severity of menstrual bleeding will be measured and compared by means of visual analogue scale and Higam methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810303109N1**
Registration date: **2010-06-12, 1389/03/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-06-12, 1389/03/22

Registrant information

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Fatemeh Zeraati
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Hamadan Medical University

Expected recruitment start date

2010-01-12, 1388/10/22

Expected recruitment end date

2011-01-12, 1389/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of herbal extrats (Fenellin & Vitagnus) and Mefenamic acid in the treatment of primary dysmenorrhea and menstrual bleeding

Public title

Effect of herbal extracts in primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Female student with primary dysmenorreha Exclusion criteria: 1-Any systemic disease

such as liver, kidney, thyroid and coagulation disease 2- Hypersensitivity to drug 3- Use of analgesic drugs during the study 4- Use of OCP or IUD

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committee of Hamadan University of Medical Sciences

Street address
Deputy dean of Research, Medical School, Hamadan University of Medical Sciences

City
Hamadan

Postal code

Approval date
empty

Ethics committee reference number
13681017

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

Timepoint
The day before the menstrual cycle starts and day 1, 2, and 3 of the cycle in three successive cycles

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Menstrual bleeding

Timepoint
Day 1, 2, and 3 of the menstrual cycle in three successive cycles

Method of measurement
Using Higam method

Intervention groups

1

Description
Group 1 will receive Fenellin, 30 drops every 4 hours beginning one day before the start of the cycle until the third day

Category
empty

2

Description
Group 4 will receive Placebo, 30 drops every 4 hours beginning one day before the start of the cycle until the third day

Category
Placebo

3

Description
Group 2 will receive Vitagnus 40 once a day in the morning beginning one day before the start of the cycle until the third day

Category
Treatment - Drugs

4

Description
Group 3 will receive Mefenamic acid 250 mg capsules every 4 hours beginning one day before the start of the cycle until the third day

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical School
Full name of responsible person
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
Street address
Medical School, Deputy dean for Research
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

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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