

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

Name

Fatemeh Zeraati

Name of organization / entity

Hamadan Medical University

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 6295

Email address

zeraati@umsha.ac.ir

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

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Fatemeh Shobeiri

Position

Ph.D. Maternal and Child Health

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