

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the Effect of Menstrugloe Capsule and Vitamin E on Primary Dysmenorrhea

Protocol summary

Summary

The aim of this study is to determine the Effect of Menstrugloe capsule and Vitamin E on Primary Dysmenorrhea of students in Hamadan University of Medical Sciences, Hamadan, Iran in 2017. The present study is a clinical trial study with three-group design with two stages of before and after intervention. The research Community consists of students in Hamadan University of Medical Sciences. The research sample consisted of students in Hamadan University of Medical Sciences who had inclusion criteria (ages 18-30 and having Primary Dysmenorrhea) in the research environment (120 people) were enrolled in the study. Written informed consent will obtain from all participants. The participants will be randomly allocated to one of three oral treatments groups: Menstrugloe capsule (500mg/day) or Vitamin E (200mg/day) or Placebo. Demographic Questionnaire and the Dysmenorrhea Multidimensional Speech Scale and McGill Pain ruler are used. Severity of Primary Dysmenorrhea will compare the three groups before and after treatment intervention end of two months. Data were analyzed using descriptive and inferential statistical methods.

General information

Acronym

Primary Dysmenorrhea

IRCT registration information

IRCT registration number: **IRCT201707306888N18**

Registration date: **2017-09-02, 1396/06/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-02, 1396/06/11

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 6051

Email address

shobeiri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences, Hamadan, Iran

Expected recruitment start date

2017-09-01, 1396/06/10

Expected recruitment end date

2017-12-01, 1396/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Menstrugloe Capsule and Vitamin E on Primary Dysmenorrhea

Public title

Comparison of the Effect of Menstrugloe Capsule and Vitamin E on Primary Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Student; Age between 18-30 years; Having Primary Dysmenorrhea; Lack of allergy to drugs, Exclusion criteria: Allergy to drugs; Unwillingness to continue cooperation.

Age

From **18 years** old to **30 years** old

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**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Department of Research and Technology, Fahmideh street, Hamadan

City

Hamadan

Postal code

6517838698

Approval date

2017-07-29, 1396/05/07

Ethics committee reference number

IR. UMSHA.REC.1396.341

Health conditions studied**1****Description of health condition studied**

Dysmenorrhea

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes**1****Description**

Severity of dysmenorrhea

Timepoint

Before the intervention and two month after the intervention

Method of measurement

Dysmenorrhea Multidimensional Speech Scale and McGill Pain ruler

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Prescription oral Menstrugloe capsule (500mg/day), produced by Gol Daroo Company for 2 months.

Category

Treatment - Drugs

2**Description**

Intervention group: Prescription oral Vitamin E (200mg/day), produced by Daana Pharmacy Company for 2 months.

Category

Treatment - Drugs

3**Description**

Control group: Prescription oral Placebo (1 capsule /day), produced by Gol Daroo Company for 2 months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Shobeiri

Street address

Street Shahid Fahmideh, Hamedan University of Medical Sciences

City

Street Shahid Fahmideh, Hamedan University of Medical Sciences

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Research and Technology Deputy, Hamadan
University of Medical Sciences, Shahid Fahmideh
street, Hamadan

City

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technology, 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

PhD Maternal and Child Health / Professor

Other areas of specialty/work**Street address**

Hamadan University of Medical Sciences, Faculty of
Nursing and Midwifery, Shahid Fahmideh street,
Hamadan

City

Hamadan

Postal code**Phone**

+98 81 3822 0123

Fax**Email**

fshobeiri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Fatemeh Shobeiri

Position

PhD Maternal and Child Health / Professor

Other areas of specialty/work**Street address**

Hamadan University of Medical Sciences, Faculty of
Nursing and Midwifery, Shahid Fahmideh street,
Hamadan

City

Hamadan

Postal code**Phone**

+98 81 3838 0150

Fax**Email**

fshobeiri@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Fatemeh Shobeiri

Position

PhD Maternal and Child Health / Professor

Other areas of specialty/work**Street address**

Hamadan University of Medical Sciences, Faculty of
Nursing and Midwifery, Shahid Fahmideh street,
Hamadan

City

Hamadan

Postal code**Phone**

00

Fax**Email****Web page address**

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