

# 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**

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**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*