Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Oct 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 befor 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. Witten 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 Universiy 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

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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