

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The Study on the Effects of Echium amoenum compared to placebo on severity of Pre Menstrual Syndrome (PMS) signs among college students

Protocol summary

Summary

This double-blind randomized clinical trial will be conducted to assess the effect of Echium Amoenum on premenstrual symptoms. The study population comprise 84 female students having premenstrual symptoms according to PSST (Premenstrual Symptoms Screening Tool) questionnaire and satisfied the inclusion criteria. The participants will be randomly assigned into Echium amoenum or placebo group. The participants in the intervention group will receive Echium amoenum capsule while participants in the control group will receive placebo with the same dosage. The outcome measures in this study are premenstrual symptoms, as obtained through the PSST questionnaire before and during the intervention. At the end of the study, two premenstrual syndrome sign scores will be obtained for every participant (1 before intervention to recognize the eligible samples and after 2 cycle intervention).

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110822779N3**

Registration date: **2015-11-27, 1394/09/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-27, 1394/09/06

Registrant information

Name

Maryam Farahmand

Name of organization / entity

Tehran University of Medical Sciences

Country

Scientific title

The Study on the Effects of Echium amoenum compared to placebo on severity of Pre Menstrual Syndrome (PMS) signs among college students

Public title

The Study on the Effects of Echium amoenum compared to placebo on severity of Pre Menstrual Syndrome (PMS) signs among college students

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-35 years old; having regular menstrual cycles; experience of PMS symptoms; not smoking; alcohol or drug usage; willingness to participate in the study; completed a written informed consent. Exclusion criteria: pregnancy; lactation; menstrual cycle irregularity; medical disease; hormonal method of contraception; developing tensions and severe psychological crisis within the past 6 months.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Keshavarz Blvd., corner of Ghods St.

City
Tehran

Postal code

Approval date
2015-06-16, 1394/03/26

Ethics committee reference number
IR.TUMS.REC.1394.59

Health conditions studied

1

Description of health condition studied
Pre Menstrual Syndrome (PMS)

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Premenstrual syndrome severity

Timepoint

Monthly

Method of measurement
Premenstrual Symptoms Screening Tool (PSST) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Oral administration of 150 mg Echium amoenum capsule for 2 menstrual cycle 3 times a day

Category
Treatment - Drugs

2

Description

Placebo capsules had 150mg starch with the same shape for 2 menstrual cycle 3 times a day

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Students' Dorms, Tehran University of Medical Sciences

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person
Kardan Moghaddam

Street address
Keshavarz Blvd., corner of Ghods St.

City
Tehran

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, Tehran 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***City**

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Nursing Midwifery Care Research Center

Full name of responsible person

Reza negarandeh

Position

Professor

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PhD candidate

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Nursing and Midwifery , Nosrat st., Tohid sq.**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*