

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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).

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

Iran (Islamic Republic of)

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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

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

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Keshavarz Blvd., corner of Ghods St.

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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***Person responsible for general inquiries****Contact****Name of organization / entity**

Nursing Midwifery Care Research Center

Full name of responsible person

Reza negarandeh

Position

Professor

Other areas of specialty/work**Street address**Nursing Midwifery Care Research Center, Faculty of
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Nursing Midwifery Care Research Center

Full name of responsible person

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Position

PhD candidate

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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***Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing Midwifery Care Research Center

Full name of responsible person

Maryam Farahmand

Position

PhD candidate

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