

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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)

###### Phone

+98 21 6642 1685

###### Email address

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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

**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*

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

Nursing Midwifery Care Research Center

**Full name of responsible person**

Reza negarandeh

**Position**

Professor

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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*