

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

The Study on the Effects of Licorice 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 Licorice 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 Licorice or placebo group. The participants in the intervention group will receive Licorice 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: **IRCT2015061722779N1**
Registration date: **2015-06-29, 1394/04/08**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-29, 1394/04/08

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Sciences

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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 Licorice compared to placebo on severity of Pre Menstrual Syndrome (PMS) signs among college students

Public title

Effects of Licorice on premenstrual disturbances

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria: age 18-35 years; 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 110 mg licorice capsule for 2 menstrual cycle 3 times a day

Category

Treatment - Drugs

2

Description

Placebo capsules had 110mg starch with the same shape for 2 menstrual cycle 3 times a day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran dorms

Full name of responsible person
Maryam Farahmand

Street address
Nursing Midwifery Care Research Center, Faculty of Nursing and Midwifery , Nosrat st., Tohid sq.

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Sponsors / Funding sources

1

Sponsor

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

Full name of responsible person
Reza Negarandeh

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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
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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