Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Study on the Effects of Pimpinella anisum 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 Pimpinella anisum 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 Pimpinella anisum or placebo group. The participants in the intervention group will receive Pimpinella anisum 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: **IRCT2015110822779N2**
Registration date: **2015-12-11, 1394/09/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-12-11, 1394/09/20

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
m-farahmand@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-01-04, 1395/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

The Study on the Effects of Pimpinella anisum compared to placebo on severity of Pre Menstrual signs among college students

Purpose

Treatment

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. Tehran
City
Tehran
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
IR.TUMS.REC.1394.59

Health conditions studied

1

Description of health condition studied
Premenstrual Syndrome
ICD-10 code
N94.3
ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Premenstural 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 Pimpinella anisum 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
Kamrava Dorm
Full name of responsible person
Maryam Farahmand
Street address
No.16, Gord Afarid St., Karegar st.
City
Tehran

2

Recruitment center
Name of recruitment center
Somayeh Dorm
Full name of responsible person
Maryam Farahmand
Street address
Shahid Beheshti St., Shariati St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vida Kardan Moghaddam

Street address
Keshavarz Blvd., corner of Ghods St. Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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 Nursing and Midwifery , Nosrat st., Tohid sq.
City
Tehran
Postal code
Phone
+98 21 6642 1685
Fax
Email
rnegarandeh@tums.ac.ir
Web page address

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
Other areas of specialty/work
Street address
Nursing Midwifery Care Research Center, Faculty of Nursing and Midwifery , Nosrat st., Tohid sq.
City
Tehran
Postal code
Phone
+98 21 6642 1685
Fax
Email
mfarahmand14@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Nursing Midwifery Care Research Center
Full name of responsible person
Maryam Farahmand
Position
PhD candidate
Other areas of specialty/work
Street address
Nursing Midwifery Care Research Center, Faculty of Nursing and Midwifery , Nosrat st., Tohid sq.
City
Tehran
Postal code
Phone
00
Fax
Email
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