Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Piperine, Vitamin E, and Piperine with Vitamin E Oral Capsules Effects on Premenstrual Syndrome among Dormitory Students

Protocol summary

Summary

This randomized control trial is a triple-blind study with the aim of Comprising the effect of Piperine, Vitamin E, and Piperine with Vitamin E Oral Capsules on Premenstrual Syndrome (PMS), which will be conducted in students, who live in Iran University of Medical Sciences dorms. Regarding to premenstrual profile 2005 and satisfied the inclusion criteria such as not using any kind of treatment that influence the premenstrual syndrome, no history of allergy to any food...180 volunteer students with PMS will randomly be divided to four groups and will involve in the study. Each group will receive two same shape packets during two menstrual cycles, and will be requested to complete the premenstrual profile 2005 at the same time of taking orally two capsules in a day from each packet, for two weeks, a week before menstruation. Group A will receive one packet of capsules, each capsule contained 8 mg of Piperine and another packet of capsules, each capsule contained 50 mg of Gelatin, Group B will receive one packet of capsules, each capsule contained 400 International Units of Vitamin E and another one packet of capsules, each capsule contained 50 mg of Gelatin, Group C will receive one packet of capsules, each capsule contained 8 mg of Piperine and another packet of capsules, each capsule contained 400 International Units of Vitamin E, Group D will receive two packets of capsules, each capsule contained 50 mg of Gelatin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508022172N19**
Registration date: **2016-01-04, 1394/10/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-01-04, 1394/10/14

Registrant information

Name
Simin Taavoni
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8820 8161
Email address
staavoni@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Iran University of Medical Sciences

Expected recruitment start date

2016-01-05, 1394/10/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Piperine, Vitamin E, and Piperine with Vitamin E Oral Capsules Effects on Premenstrual Syndrome among Dormitory Students

Public title

Comparison of Piperine, Vitamin E, and Piperine with Vitamin E Oral Capsules Effects on Premenstrual Syndrome

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age between 18 and 35 years old; being single; being healthy regarding to their self-report and physical examination; having regular menstrual cycles (22-35 days and 2-7 days duration); having premenstrual syndrome (PMS) in 2 past cycles (no sever syndrome); no history of allergy to any food; not taking any medicine; not taking any complements; not smoking, alcohol or drug usage; no history of pregnancy. Exclusion criteria: use of any kind of drug or therapy for symptom relief during the study intervention; side effects during intervention for example allergy; change in diet or physical exercise program during the study; any kind of crisis in participant or her family; not taking capsules more than 7 days in 2 cycles
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences Department
Street address
Shahid Hemmat Highway, Iran University of Medical Sciences, Headquarters ,- 5th Floor
City
Tehran
Postal code
Approval date
2015-12-27, 1394/10/06
Ethics committee reference number
IR.IUMS.REC.1394.26565

Health conditions studied

1

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

Primary outcomes

1

Description
Premenstrual syndrome (screening)
Timepoint
2 menstrual cycles
Method of measurement
premenstrual profile 2005 scale

Secondary outcomes

1

Description
Premenstrual syndrome (prevention)
Timepoint
During intervention for 2 cycles
Method of measurement
Measure by premenstrual profile 2005 scale, for duration of 2 cycles

Intervention groups

1

Description
Taking two oral capsules in a day (capsule with 8 mg Piperine, and capsule with 50 mg Gelatin) for two weeks in 2 months intervention
Category
Treatment - Drugs

2

Description
Taking two oral capsules in a day (capsule with 8 mg Piperine, and capsule with 400 IU vitamin E) for two weeks in 2 months intervention
Category
Treatment - Drugs

3

Description
Taking two oral capsules in a day (capsule with 400 IU vitamin E, and capsule with 50 mg Gelatin) for two weeks in 2 months intervention
Category
Treatment - Drugs

4

Description
Taking two oral capsules of 50 mg Gelatin in a day for two weeks in 2 months intervention
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amol dorm
Full name of responsible person
Miss Ahmadi
Street address
No: 138, Amol St., Shareati Ave. Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
Shaqhayeqh dorm
Full name of responsible person
Miss Amiri far
Street address
No:27/29, Motahari Ave. Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research and technology, Iran University of Medical Sciences
Full name of responsible person
Mis Azvan
Street address
Shahid Hemmat Highway, Iran University of Medical Sciences, Headquarters ,- 5th Floor
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 and technology, Iran 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
Iran University of Medical Sciences
Full name of responsible person
Simin Taavoni
Position
PhD student in Medical Education, School of Medicine, Tehran University of Medical Sciences, M. Sc i
Other areas of specialty/work
Street address
3rd Floor, No.12, Nadjmabady St. Kazeroon St. Mirdamad Ave Tehran
City
Tehran
Postal code
Phone
+98 21 6692 1228
Fax
Email
staavoni14@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Simin Taavoni
Position
PhD student in Medical Education, School of Medicine, Tehran University of Medical Sciences, M. Sc i
Other areas of specialty/work
Street address
3rd Floor, No.12, Nadjmabady St. Kazeroon St. Mirdamad Ave Tehran
City
Tehran
Postal code
Phone
+98 21 6692 1228
Fax
Email
staavoni14@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Simin Taavoni

Position

PhD student in Medical Education, School of Medicine, Tehran University of Medical Sciences, M. Sc i

Other areas of specialty/work

Street address

3rd Floor, No.12, Nadjmabady St. Kazeroon St. Mirdamad Ave Tehran

City

Tehran

Postal code

Phone

+98 21 6692 1228

Fax

Email

staavoni14@yahoo.com

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