Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluate the effect of Vitagnus on premenstrual syndrome in female students of Shahid Chamran dormitory

Protocol summary

Summary

This study aimed to determine the effect of Vitagnus on premenstrual syndrome in female students of Shahid Chamran dorm, and it was conducted as a double-blind clinical trial.. Inclusion criterion: Female students suffering PMS with regular menstrual cycle and exclusion criteria: current psychotherapy, breast feeding/pregnancy, taking sexual hormones, having stress in the past three months (e.g. death, marriage or surgery of close relatives),. In this study, after completing the questionnaire twice during three consecutive menstrual cycles, 72, daughter of Shahid Chamran dormitory students who 25_18 years of age, suffering from moderate to severe premenstrual syndrome and the conditions for inclusion were selected and then randomly divided into experimental and control groups were 36. Case group was prescribed with 40 drops of Vitagnus daily for three menstrual cycles, while the control group was given placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102219632N1**
Registration date: **2015-02-04, 1393/11/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-02-04, 1393/11/15

Registrant information

Name

Parvaneh Mousavi

Name of organization / entity

Ahvaz University Of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Reseach Deputy of Ahvaz University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the effect of Vitagnus on premenstrual syndrome in female students of Shahid Chamran dormitory

Public title

Vitagnus effect on premenstrual symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: students with premenstrual syndrome with regular menstrual cycle. exclusion criteria: Psychotherapy with pregnancy or breastfeeding; use of hormones; stress in the recent quarter such as marriage or the death of someone close surgery; patients taking certain medications such as dopamine antagonists used

Age

From **18 years** old to **25 years** old

Gender

Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **72**
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
Ahvaz University of Medical Sciences
Street address
Ahvaz University of Medical Sciences، Esfand Street، Golestan
City
Ahvaz
Postal code
Approval date
2003-01-21, 1381/11/01
Ethics committee reference number
278

Health conditions studied

1

Description of health condition studied
Premenstrual Syndrome
ICD-10 code
N94.3
ICD-10 code description
Unspecified condition associated with female genital organs and menstrual cycle

Primary outcomes

1

Description
the severity of the symptoms of premenstrual syndrome
Timepoint
one؛ two Three months after intervention
Method of measurement
Recorded daily symptoms of PMS

Secondary outcomes

1

Description
Side effects include itching, dizziness, stomach pain, diarrhea
Timepoint
Two weeks until 1 mounth
Method of measurement
Phone calls and monthly views

Intervention groups

1

Description
Five finger test group oral drops to 40 drops a day for three menstrual cycles
Category
Treatment - Drugs

2

Description
A placebo control group, the intervention takes place
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Girls' dormitory University of Shahid Chamran
Full name of responsible person
Parvane Mousavi
Street address
Girls' dormitory University Of Shahid Chamran، Esfand Street، Golestan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University Of Medical Sciences
Full name of responsible person
Kouroosh Zare
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Esfand Street، Golestan
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Ahvaz
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
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Person responsible for updating data

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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