Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

The Impact Of Valerian Root Extract On Pre Menstural Syndrome Symptoms

Protocol summary

Summary

The aim of this study is to assess The Impact of Valerian Root Extract On PreMenstural Syndrome Severity of Symptoms. Inclusion criteria: Single, 18-35 years,Having regular menstrual cycles and normal 21-35 and Duration of 7-3 days in the last 6 months, Lack of physical and emotional illness known And use of a Use of certain medications,no Occurrence of stressful events during the 3 months before study And diagnosis of premenstrual syndrome according to the Daily Form, Failure to participate in research studies of similar. Exclusion criteria of the study, Lack of volunteers willing to Continued drug use,Occurrence drug allergies, Stopping the medication for a week in the first cycle and irregular use of medication in cycles 2 and 3 for two days,Understanding of physical and mental illness during the study, Married during the study, Relatives death relatives and had surgery during the past two months. This study was conducted on 100 students at dormitory of University - Tonekabon Branch. Students initially recorded daily symptoms for two menstrual cycles completed. Students with random assignment to treatment groups (capsule Sedamin 530 mg) and placebo control groups. Each student taking the drug daily for three consecutive menstrual cycle taking two last seven days And her symptoms were recorded daily symptom questionnaire. Consequence of this Study for the students is the reduction of the severity of mental, physical and behavior symptoms of premenstrual syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211179463N5**
Registration date: **2013-04-14, 1392/01/25**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-04-14, 1392/01/25

Registrant information

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Zahra Behboodi Moghadam
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Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact Of Valerian Root Extract On Pre Menstural Syndrome Symptoms

Public title

The Impact Of Valerian Root Extract On Pre Menstural Syndrome Symptoms

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Single, 18-35 years, Having regular menstrual cycles and normal 21-35 and Duration of 7-3 days in the last 6 months, Lack of physical and emotional illness known And use of a Use of certain medications, no Occurrence of stressful events during the 3 months before study And diagnosis of premenstrual syndrome according to the Daily Form, Failure to participate in research studies of similar. Exclusion criteria of the study, Lack of volunteers willing to Continued drug use, Occurrence drug allergies, Stopping the medication for a week in the first cycle and irregular use of medication in cycles 2 and 3 for two days, Understanding of physical and mental illness during the study, Married during the study, Relatives death relatives and had surgery during the past two months. and third cycles are some criteria for stopping the study ; Understanding of physical and mental illness during the study; Married during the study; Relatives death and had surgery during the past two 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: **100**

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
factulty of nersing and midwifery of Tehran University of Medical Sciences

City
tehran

Postal code

Approval date
2013-03-03, 1391/12/13

Ethics committee reference number
3183/130/91/د

Health conditions studied

1

Description of health condition studied
Premenstural Syndrome

ICD-10 code
F59

ICD-10 code description
Unspecified behavioural syndromes associated with physiological disturbances and physical factors

Primary outcomes

1

Description
Reduction in physical symptoms (headache, breast swelling and tenderness, back pain, abdominal pain, muscle pain, Overweight, swelling of extremities, nausea, bloat)

Timepoint
One month, two months, three months after intervention

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Reduction in mood symptoms (anxiety and Worry, Restlessness, Nervous tension, Get angry, Snappish, irritableity, depression Withdrawal and irritability and sadness, crying for no reason, feeling alone, Freak out, Behavioral inconsistency)

Timepoint
One month, two months, three months after intervention

Method of measurement
Questionnaire

2

Description
Reduction in behavioral symptoms (fatigue lack of energy, insomnia, difficulty concentrating, increased appetite)

Timepoint
One month, two months, three months after intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
in imterventional groug:Sedamin Capsules, 530 mg, 2 times a day, orally for 3 months

Category
Placebo

2

Description
in control group:Placebo capsules, 2 times a day, orally for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
dormitory of Islamic Azad University - Tonekabon Branch
Full name of responsible person
Roghaye shiroodgholami
Street address
tonekabon-valiaba Islamic Azad University - Tonekabon Branch
City
tonekabon

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Science, vice chancellor for research(primary sponsor
Full name of responsible person
Dr. Akbar Fotuhi
Street address
khods street, keshavarz boulevard
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 Science, vice chancellor for research(primary sponsor
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
Tehran University of Medical Science
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Position
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Person responsible for updating data

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faculty of nursing and midwifery of tehran university of medical sciense
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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