

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Impact Of Valerian Root Extract On Pre Menstrual Syndrome Symptoms

Protocol summary

Summary

The aim of this study is to assess The Impact of Valerian Root Extract On PreMenstrual 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

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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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 Menstrual Syndrome Symptoms

Public title

The Impact Of Valerian Root Extract On Pre Menstrual 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

faculty of nursing and midwifery of Tehran University of Medical Sciences

City

tehran

Postal code

Approval date

2013-03-03, 1391/12/13

Ethics committee reference number

3183/130/91/3

Health conditions studied

1

Description of health condition studied

Premenstrual 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, irritability, 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 interventional group: 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 centers1**Recruitment center****Name of recruitment center**dormitory of Islamic Azad University - Tonekabon
Branch**Full name of responsible person**

Roghaye shiroodgholami

Street addresstonekabon-valiaba Islamic Azad University -
Tonekabon Branch**City**

tonekabon

Sponsors / Funding sources1**Sponsor****Name of organization / entity**Tehran University of Medical Science, vice chancellor
for research(primary sponsor)**Full name of responsible person**

Dr. Akbar Fotuhi

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khods street, keshavarz boulevard

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceTehran 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

Full name of responsible person

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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