Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the effect of vitex agnus castus on treatment of premenstrual syndrome among students of Tehran University of Medical Sciences and Tehran University

Protocol summary

Summary

Objective: to evaluate the effect of Vitex on treatment of premenstrual syndrome. Design: Randomized, double blind, placebo controlled, parallel group comparison. 116 students of Tehran University of Medical Sciences and Tehran University living in dormitory were included in this study. Participants underwent a preliminary screening interview, completed Daily Symptom Rating (DSR) for two cycles, and attended in medical screening visit and screening for depression by Beck questionnaire. 116 eligible students were randomly divided in two groups of 58 people. Participants took tablets of Vitex daily or matching placebo for two cycles. Finally 49 participants in active and 50 in placebo group completed study. Inclusion criteria: Single students of at least 18 years old, with regular menstruation and confirmed diagnosis of pms were included. Diagnosed physical or mental diseases, using hormonal drugs, vitamins, herbal drugs and participation in other same trials were among exclusion criteria. Main Outcome Measures: psychological, physical and total symptoms of premenstrual syndrome were assessed before (two screening cycles) and after treatment (two treatment cycles) via Daily Symptoms Rating (DSR) contain 18 symptoms of premenstrual syndrome (10 psychological and 8 physical symptoms).

General information

Acronym

Evaluating the effect of vitex agnus castus on treatment of premenstrual syndrome

IRCT registration information

IRCT registration number: **IRCT201101035541N1**
Registration date: **2011-03-31, 1390/01/11**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-03-31, 1390/01/11

Registrant information

Name

Maryam Moradi

Name of organization / entity

Australian National University

Country

Australia

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0061430679650

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2006-06-22, 1385/04/01

Expected recruitment end date

2007-03-06, 1385/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of vitex agnus castus on treatment of premenstrual syndrome among students of Tehran University of Medical Sciences and Tehran University

Public title

Evaluating the effect of vitex agnus castus on treatment

of premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age 18 and above 2- Single 3- Regular menstruation (interval: 24-35 days, duration: 2-8 days) in last year 4- Contemporary diagnosis of pms based on DSM-IV 5- Confirmed diagnosis of pms based on two screening cycles Exclusion criteria: 1- Diagnosed physical or mental diseases 2- Using hormonal drugs, agonist or antagonist of dopamine ,or vitamins 3- Using antidepressant or herbal drugs 4- Participation in other same trials

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In treatment stage 116 eligible participants were randomly divided to two groups. Participants took vitex agnus castus one tablet daily or matching placebo for two cycles.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research of Tehran University of Medical Sciences

Street address

6th Floor, Central Organization of University,Ghods Street,Keshavarz BLV,Tel:88987381

City

Tehran

Postal code

فاکس:0098218898966

Approval date

2006-10-10, 1385/07/18

Ethics committee reference number

6673/132

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

total symptoms of premenstrual syndrome

Timepoint

before treatment (two screening cycles)and after treatment (two treatment cycles)

Method of measurement

Daily Symptoms Rating(DSR)contain 18 symptoms of premenstrual syndrome (10 psychological and 8 physical symptoms)

2

Description

psychological symptoms of premenstrual syndrome

Timepoint

before treatment (two screening cycles)and after treatment (two treatment cycles)

Method of measurement

Daily Symptom Rating (DSR) (contain 10 psychological symptoms)

3

Description

physical symptoms of premenstrual syndrome

Timepoint

before treatment (two screening cycles)and after treatment (two treatment cycles)

Method of measurement

Daily Symptom Rating (DSR) (contain 8 physical symptoms)

Secondary outcomes

1

Description

side effects

Timepoint

in two treatment cycles

Method of measurement

through check list of side effects

Intervention groups

1

Description
Participants in drug group took tablet of vitex agnus castus made by Goldaru pharmaceutical Company in Esfahan (contain 3.2- 4.8 mg dry extract of vitex fruit, equal 0.42-0.58 mg Aucubin), one tablet daily for two cycles.
Category
Treatment - Drugs

2

Description
Participants in placebo group took tablet of placebo made by Goldaru Pharmaceutical Company in Esfahan (contain Magnesium Astyaarat 1 % and Starch), one tablet daily for two cycles.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitory of Tehran University of Medical Sciences
Full name of responsible person
Maryam Moradi
Street address
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2

Recruitment center
Name of recruitment center
Dormitory of Tehran University
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Research Chancellor
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6th Floor, Central Organization of University,Ghods Street,Keshavarz BLV,Tel:88987381
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
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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