

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

Phone

0061430679650

Email address

maryam.moradi@anu.edu.au

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

0098218898966: فاکس

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

Enghelab Square,Koye Daneshghah,

City

Tehran

2

Recruitment center

Name of recruitment center

Dormitory of Tehran University

Full name of responsible person

Maryam Moradi

Street address

Enghelab Square,Koye Daneshghah,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Research Chancellor

Street address

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

Australian National University

Full name of responsible person

Maryam Moradi

Position

Ms of Midwifery and PhD candidate at Australian National University

Other areas of specialty/work

Street address

Canberra,Australian National University

City

Canberra

Province

ACT

Postal code

Phone

061262443655

Fax

061262444960

Email

maryam.moradi@anu.edu.au

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nursing and Midwifery Faculty of Tehran University of Medical Sciences

Full name of responsible person

Minoos Pakgohar

Position

Faculty member of Nursing and Midwifery Faculty of Tehran University of Medical Sciences

Other areas of specialty/work

Street address

Tohid Square, Nursing and Midwifery Faculty of Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 6693 7120

Fax

+98 21 6696 5405

Email

mpakgohar@razi.tums.ac.ir

Web page address**Postal code****Phone**

+98 21 6693 7120

Fax

+98 21 6696 5405

Email

mpakgohar@razi.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Nursing and Midwifery faculty of Tehran University of
Medical Sciences

Full name of responsible person

Minoo Pakgohar

Position

faculty member of Nursing and Midwifery faculty of
Tehran University of Medical Sciences

Other areas of specialty/work**Street address**

Tohid Square, Nursing and Midwifery faculty of Tehran
University of Medical Sciences

City

Tehran

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