

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation the effect of salvia officinalis on the Symptoms of Premenstrual Syndrome in the Dormitories Students of Shahid Beheshti University of Medical Science and Health Services

Protocol summary

Summary

This randomized, triple-blind clinical trial is with placebo control group, that is performing following the approval by the ethics committee of Shahid Beheshti University of Medical Sciences, International Branch, Tehran, Iran, In doing so, the researcher visit the students in their separate rooms, introduce herself and explain the objectives of the study, and invite them to cooperate in the survey. Then students whom being single, age within 18e35 years, normal body mass index, regular menstrual cycle (21e35 days), with diagnosed PMS, no physical or psychological ill conditions, not on medication (hormonal, vitamins, herbal, antidepressant, aspirin, or warfarin), no history of allergy to herbal drugs, no sad event occurrence, no surgical operation during the last six months, not being a professional athlete, presence of at least five symptoms based on DSM-IV (Diagnostic and Statistical Manual of Mental Disorders-fourth edition) for PMS diagnosis with confirmed one symptom out of the first four symptoms including (1. Feeling sad, hopeless or selfdeprecating, 2. Feeling tense, anxious, or "on edge", 3. Marked lability of mood, interspersed with frequent tearfulness, 4. Persistent irritability, anger and increased interpersonal conflicts, 5. Decreased interest in usual activities that may be associated with withdrawal from social relationships), not being depressed based on Beck questionnaire. Those with the above mentioned criteria were entered into the study. An informed written consent was also given by each participant. PMS daily form: The participants filled the daily form of PMS consisting of 30 items on the symptoms divided into 15 physical ones including breast tenderness, headache, vertigo, bloating, weight gain, swollen extremities, palpitation, arthralgia and myalgia, sweating and chills, change in bowel movement, nausea, acne, recurrent herpes like infection, flushing and hotness, pelvic and abdominal pains and lassitude, fatigue and low energy state and 15

psychological, emotional and behavioral ones consisting of depression, anxiety, tension, emotional and affective instability, anger, irritability, loss of interest in daily routine activities, difficulty in concentration, forgetfulness, unjustified tendency to cry, avoiding socialization and contacts, preference for solitude, feeling of being out of control, change in sleeping pattern, change in appetite or overeating, desire to eat sweets and salt, and tendency to commit suicide. In doing so, the mean of severity was obtained and converted into percentage. Based on the percentages, the participants were divided into three groups; those with mild symptoms (below 33%), medium group (between 33% and 66%), and severe group (above 66%). Then with using Eexcel Software divided into two 45 person groups. And after obtaining the written consent of their medicines (45 person 3 capsules daily intake of 500 mg sage and 45 person 3 capsules of intake placebo) will be provided.

General information

Acronym

PMS (premenstrual syndrome)

IRCT registration information

IRCT registration number: **IRCT201508268801N20**

Registration date: **2016-05-30, 1395/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-30, 1395/03/10

Registrant information

Name

Masoumeh Simbar

Name of organization / entity

Shahid Beheshti University for Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Shahid Beheshti University for Medical Sciences

Expected recruitment start date
2015-09-11, 1394/06/20

Expected recruitment end date
2016-03-10, 1394/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of salvia officinalis on the Symptoms of Premenstrual Syndrome in the Dormitories Students of Shahid Beheshti University of Medical Science and Health Services

Public title
Evaluation the effect of salvia officinalis on premenstrual syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: being single; age between 18-35 years old; normal body mass index; regular menstrual cycle (21-35 days), with diagnosed PMS; no physical or psychological ill conditions; not on medication (hormonal, vitamins, herbal, antidepressant, aspirin, or warfarin); no history of allergy to herbal drugs; no sad event occurrence; no surgical operation during the last six months; not being a professional athlete; presence of at least five symptoms based on DSM-IV (Diagnostic and Statistical Manual of Mental Disorders-fourth edition) for PMS diagnosis with confirmed one symptom out of the first four symptoms including (1. Feeling sad, hopeless or selfdeprecating, 2. Feeling tense, anxious, or "on edge", 3. Marked lability of mood, interspersed with frequent tearfulness, 4. Persistent irritability, anger and increased interpersonal conflicts, 5. Decreased interest in usual activities that may be associated with withdrawal from social relationships); not being depressed based on Beck questionnaire. Those with the above mentioned criteria were entered into the study. An informed written consent was also given by each participant. Exclusion criteria: allergy to drugs; improper use of capsules and developing a significant disease and taking medications during the study.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Shahid Beheshti University of Medical Sciences

Street address

Medical Sciences University of Shahid Beheshti
Nursing and Midwifery faculty of Shahid Beheshti, Vali Asr intersection prayer in front of the Rajai Hospital
Beheshti Department of Nursing and Midwifery

City

Tehran

Postal code

1985717443

Approval date

2015-11-01, 1394/08/10

Ethics committee reference number

IR.SBMU.PHNM.1394.181

Health conditions studied

1

Description of health condition studied

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

The severity of physical symptoms of premenstrual

syndrome

Timepoint

Pre intervention, first month after intervention, second month after intervention

Method of measurement

Form a provisional diagnosis of premenstrual syndrome from DSM5

2

Description

The severity of psychological symptoms of premenstrual syndrome

Timepoint

Pre intervention, first month after intervention, second month after intervention

Method of measurement

Daily form of severity of premenstrual syndrome

3

Description

The severity of symptoms of premenstrual syndrome

Timepoint

Pre intervention, first month after intervention, second month after intervention

Method of measurement

Daily form of severity of premenstrual syndrome

Secondary outcomes

1

Description

Side effects

Timepoint

First month after intervention, second month after intervention

Method of measurement

Questionnaire of effects and side effects of medication

Intervention groups

1

Description

Salvia officinalis extract, 500 mg capsule oral, 21st day till the 5th day of next cycle one capsule daily

Category

Treatment - Drugs

2

Description

Placebo, 500 mg capsule oral, 21st day till the 5th day of next cycle one capsule daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Dormitory

Full name of responsible person

Roghayeh Abdnezhad

Street address

Vali- Asr Street at the corner of the Niayesh Street
Opposite the Rajaei heart hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Yas Dormitory

Full name of responsible person

Roghayeh Abdnezhad

Street address

Vanak Square, Khodami Street, Opposite Maskan Bank, No27

City

Tehran

3

Recruitment center

Name of recruitment center

Gol Narges Dormitory

Full name of responsible person

Roghayeh Abdnezhad

Street address

Lower than the Vanak Square, Vali Asr Street,
Opposite the Saei Park, Abshar Alley, No 75

City

Tehran

4

Recruitment center

Name of recruitment center

Hazrat Zeinab Dormitory

Full name of responsible person

Roghayeh Abdnezhad

Street address

Shariati Street, Vahid Dastjerdi Street (Zafar Street),
Near the Naft Street, Adjacent to the building
Contacts, no 60

City

Tehran

5

Recruitment center

Name of recruitment center

Somayeh Dormitory

Full name of responsible person

Roghayeh Abdnezhad

Street address

Shariati Street, Motahari Intersection, Southeast Side

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Besides of Taleghani Hospital, Shahid Aarabi Street,
Yaman Street, Shahid Chamran Highway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Medical Sciences University of Shahid Beheshti

Full name of responsible person

Roghayeh Abdnezhad

Position

master of midwifery

Other areas of specialty/work

Street address

tehran.Saadat Abad,Sarv intersection,Riazi
Bakhshayesh Street, Ghaem Alley,No 19, third floor

City

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Postal code

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Phone

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Fax

Email

gilda_9a@yahoo.comgilda.9a@gmail.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoumeh Simbar

Position

PhD

Other areas of specialty/work

Street address

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Research Department

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Fax

Email

msimbar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Medical Sciences University of Shahid Beheshti

Full name of responsible person

Roghayeh Abdnezhad

Position

Master of Midwifery

Other areas of specialty/work

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tehran,Saadat Abad, Sarv Intersection, Riazi
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1998897756

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gilda_9a@yahoo.comgilda.9a@gmail.com

Web page address

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