Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of tablet contain mixture of extract of Vitex agnus castus, Chamomile, Echium amoenum and vitamin B6 on symptoms of Premenstrual Syndrom (PMS)

Protocol summary

Summary

This study will be performed as double-blind trial, randomized, placebo-controlled by calling on 100 females collegians of Medical Sciences of Kashan University who have premenstrual syndrome, regular menstrual cycle and no signs of systemic disease or mental and physical stress before and during the study based on standard questionnaire. Before receiving drug or placebo, they will record daily symptoms for two months and after definitive diagnosis of PMS they will be divided randomly to two groups, receiveing daily tablet containing Vitex agnus castus, Chamomile, Echium amoenum extracts and Vitamin B6 or receiving placebo tablet for two months. Tables of daily symptoms forms (physical and psychological symptoms) and DSM-IV questionnaire will be completed during this time and will be consider at the end of each month. Changes in both groups will compare to baseline and also relative to each other at the end of two months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060812438N13**
Registration date: **2015-07-22, 1394/04/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-22, 1394/04/31

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

Email address

taghizadeh_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Barij essence pharmaceutical company

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tablet contain mixture of extract of Vitex agnus castus, Chamomile, Echium amoenum and vitamin B6 on symptoms of Premenstrual Syndrom (PMS)

Public title

The effect off Vitex agnus castus, Chamomile, Echium amoenum extracts and vitamin B6 on Premenstrual Syndrom of students from Kashan University of Medical Sciences

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: regular menses period; no pregnancy or lactation; no history of psychological disorders; no alcohol or tobacco use; no history of systemic disorder;

no history of contraceptive use. Exclusion Criteria: Chronic disorder; Pelvic Inflammatory Disease (PID); taking specific drug; having stress such as having infection; inflammation and psychological disorder.

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
randomization: table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Kashan University Of Medical Sciences, Kashan

City
Kashan

Postal code

Approval date
2015-03-04, 1393/12/13

Ethics committee reference number
29/51/1/6001/پ

Health conditions studied

1

Description of health condition studied
premenstural syndrom

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
severity of premenstural syndrom

Timepoint
Baseline and End of each months

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
intervention :herbal tablet made in Barij essence pharmaceutical company contain mixture of extract of Vitex agnus castus, Chamomile, Echium amoenum and vitamin B6 ,daily,for 2 months

Category
Treatment - Drugs

2

Description
control : placebo tablet made in Barij essence pharmaceutical company contain Cellulose,daily.for 2 months

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashan University of Medical Science

Full name of responsible person
Fatemeh Abbaszadeh

Street address
School of Nursing and Midwifery,Qotbe Ravandi Boulevard, Kashan

City
Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Barij Essence Company

Full name of responsible person
Mohsen Taghizadeh

Street address
Kashan Mashhad Ardehal Road, KM44

City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Barij Essence Company
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
Kashan University of Medical Sciences
Full name of responsible person
Mohsen Taghizadeh
Position
PHD
Other areas of specialty/work
Street address
School of Medicine,Qotbe Ravandi Boulevard, Kashan
City
Kashan
Postal code
Phone
+98 31 5554 0021
Fax
Email
taghizadeh_m@kaums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Fatemeh Abbaszadeh
Position
Master of midwifery
Other areas of specialty/work
Street address
School of Nursing and Midwifery,Qotbe Ravandi Boulevard, Kashan
City
Kashan
Postal code
Phone
+98 31 5554 0021
Fax
Email
abbaszadeh_F@kaums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Barij Research Center of Medicinal Herbs
Full name of responsible person
Mahnaz.Mahlouji
Position
Clinical Expert
Other areas of specialty/work
Street address
Kashan Mashhad Ardehal Road, KM44
City
Kashan
Postal code
Phone
00
Fax
Email
mahnaz.mahlouji@yahoo.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