

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the Effect of Matricaria Chamomilla Extract and Mefenamic Acid on intensity of premenstrual syndrome

Protocol summary

Summary

Premenstrual syndrome (PMS) is one of the commonest painful problems during reproductive age among women with associated symptoms occurring before menstruation, which affects their personal lives and causes them to miss work. Some clinical trials have revealed the effects of Matricaria Chamomilla (MC) on such pains. In the present randomized, double blind, parallel -group study, we compare the effects of MC Extract and Mefenamic Acid (MA) on the intensity of PMS. In doing so, 90 students of Kazerun Islamic Azad University living in the dormitory are enrolled in the study. Participants undergo a preliminary screening interview and screening for depression using Beck questionnaire. Then, the eligible ones complete daily form for the severity of PMS for two consecutive cycles. Those diagnosed with varying intensity, are randomly divided into two groups each receiving one 100 mg capsule of MC or MA 250 mg three times daily from 21st day of menstrual cycle till the beginning of the next. Inclusion criteria are as follows: Single students of 18-35 years of age, with regular menstruation and confirmed diagnosis of PMS but without any physical or psychological diseases, using no hormonal drugs, vitamins and herbal ones. Exclusion criteria include sensitivity to drugs, incorrect use of capsules, specific disease and taking medications during the study. The main Outcome measures including severity of psychological, physical and total symptoms of PMS are assessed before (two screening cycles) and after treatment (two treatment).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201258801N2**

Registration date: **2012-03-19, 1390/12/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-19, 1390/12/29

Registrant information

Name

Masoumeh Simbar

Name of organization / entity

Shahid Beheshti University for Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2517

Email address

msimbar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

The International Branch of Shahid Beheshti University of Medical Sciences and Health Services

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-06-19, 1391/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Matricaria Chamomilla Extract and Mefenamic Acid on intensity of premenstrual syndrome

Public title

Comparison of the Effect of Matricaria Chamomilla Extract and Mefenamic Acid on intensity of premenstrual

syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Single students; 18-35 years old; With normal body mass index (19.8 -26) ; No smoking; Regular menstrual cycles(21-35 days) ; No physical disease (digestive problems like ulcers, diabetes, seizure disorders, hypothyroidism and endometriosis, and ...)and no known mental illness; At least 5 symptoms of premenstrual syndrome symptoms in a temporary form of DSMIV with necessarily one symptoms from first to fourth (1 - Markedly depressed, mood and feelings of hopelessness, 2 - Significant anxiety, tension, feelings of impatience and anxiety, 3- Significant mood instability, such as sudden sadness, 4 - Continuous and apparent anger or irritability or increased interpersonal conflicts); lack of depression based on the Beck Depression questionnaire ; no history of consumption of Certain drugs (hormones, vitamins, antidepressants, herbal medicines, aspirin, warfarin); No allergy to herbal medicines; no sad event such as death of close relatives and surgery in the past six months; Not being professional athlete. Exclusion criteria: Sensitivity to drugs; Incorrect use of capsules (two capsules daily, if not, the person is excluded); Married during the study; Having specific disease and to take medications during the study; Occurrence of a sad event such as death of close relatives and surgery; To exercise professionally.

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

Gender
Female

Phase
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)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The international Branch of Shahid Beheshti

University of Medical Sciences and Health Services

Street address
No 19, Shahid Abaspoor St, Next to Shahib Hemmat Bridge, Valiasr Ave

City
Tehran

Postal code
14155-3693

Approval date
2011-12-13, 1390/09/22

Ethics committee reference number
116/3742

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

The severity of physical 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

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 of chamomile

Timepoint

first month after intervention, second month after intervention

Method of measurement

Questionnaire of effects and side effects of medication

2

Description

side effects of mefenamic acid capsule

Timepoint

first month after intervention, second month after intervention

Method of measurement

Questionnaire of effects and side effects of medication

Intervention groups

1

Description

chamomile extract, 100 mg capsule oral, 21st day till the beginning of next cycle one capsule three times daily

Category

Treatment - Drugs

2

Description

Mefenamic Acid capsules, 250 mg capsule oral , 21st day till the beginning of next cycle one capsule three times daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh and Kosar Girls dormitories at Islamic Azad University, Kazerun Branch

Full name of responsible person

Girls dormitory residents

Street address

Islamic Azad University Kazerun Branch

City

Kazerun

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The international Branch of Shahid Beheshti University of Medical Sciences and Health Services

Full name of responsible person

Dr. Ali Haeri

Street address

No 19, Shahid Abaspoor St, Next to Shahib Hemmat Bridge, Valiasr Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The international Branch of Shahid Beheshti University of Medical Sciences and Health Services

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

The international Branch of Shahid Beheshti University Of Medical Sciences and Health Services

Full name of responsible person

Farangis Sharifi

Position

Master student of midwifery

Other areas of specialty/work

Street address

No 19, Shahid Abaspoor St, Next to Shahib Hemmat Bridge, Valiasr Ave

City

Tehran

Postal code

141553699

Phone

+98 218822090

Fax

Email

f_sharifi44@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

Full name of responsible person

Masoumeh Simbar

Position

PhD

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Valiasar street,
Niayesh Ave.

City

Tehran

Postal code

Phone

+98 21 8820 2516

Fax

Email

msimbar@yahoo.com

Web page address

Bridge, Valiasr Ave

City

Tehran

Postal code

141553693

Phone

+98 21 8820 9020

Fax

Email

f_sharifi44@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

Person responsible for updating data

Contact

Name of organization / entity

The international Branch of Shahid Beheshti
University Of Medical Sciences and Health Services

Full name of responsible person

Farangis Sharifi

Position

Master Student of Midwifery

Other areas of specialty/work

Street address

No 19, Shahid Abaspoor St, Next to Shahib Hemmat