# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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
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**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 illnes; 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 Siences 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**

premenstural syndrom

**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 mefanamic 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 Siences 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 Siences 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**
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## Person responsible for scientific inquiries

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PhD

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## Person responsible for updating data

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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*