

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of zataria-multiflora on premenstrual syndrome severity in the students of Isfahan University of Medical Sciences 1391-1392.

#### Protocol summary

##### Summary

In this clinical trial the effect of thyme essential oil (zataria-multiflora) is being evaluated in the treatment of premenstrual syndrome. Samples of 120 students of Isfahan University of Medical Sciences dormitories (age range 35-18 years) who are afflicted with the Temporary diagnostic questionnaire If this syndrome. Inclusion criteria: having a regular menstrual intervals of 35-21 days;the lack of physical disease or taking certain medications; no history of mental illness; no use of any anti depressants or hormonal drugs; no experience of stressful event during last 3 month from the beginning of the study. Exclusion criteria: hospitalization; pregnant; No experience stress during the study. In the intervention and control groups were randomly placed. The intervention group receives 2 Capsules thyme 20 mg every 12 hours (dose 80 mg daily) and controls placebo than 7 days prior to the onset of menstrual periods, taking. Severe symptoms of premenstrual syndrome symptoms daily using the form registration table for 4 cycles (2 cycles before treatment and after 2 cycles of therapy) will be completed by the subjects. After calculating the overall severity of symptoms, signs, symptoms, physical separation, emotional - affective and behavioral classification and its intensity is calculated. Consequence of this reduction in the severity of affective, physical, behavioral PMS students.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012102211212N1**  
Registration date: **2012-12-24, 1391/10/04**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-24, 1391/10/04

##### Registrant information

###### Name

Marzieh Sodouri

###### Name of organization / entity

Kasahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1555 0021

###### Email address

sodouri@kaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Kashan University of Medical Sciences

##### Expected recruitment start date

2012-10-19, 1391/07/28

##### Expected recruitment end date

2012-12-20, 1391/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of zataria-multiflora on premenstrual syndrome severity in the students of Isfahan University of Medical Sciences 1391-1392.

##### Public title

The effect of zataria-multiflora on premenstrual syndrome severity

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: Age range of 18-35 years; a mark of at least 5 of the questionnaire to detect symptoms of temporary Pms; that at least one of the five symptoms of psychiatric symptoms and the severity of each offense included within the average or more during the past two months ; having a regular menstrual cycle; lack of stressor during the previous 3 months; lack of physical illness and mental; Non-hormonal medications and anti depressants. Exclusion criteria: Persons who during the study Getting sick; being hospitalized;being pregnant; the reading experience of be stressful; those who do not use the medicine properly; or do not complete the form correctly.

## **Age**

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

## **Gender**

Female

## **Phase**

2

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **120**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Kashan University of Medical Sciences

##### **Street address**

5th Km of Ghotbe Ravandi Bulv.

##### **City**

Kashan

##### **Postal code**

87159/88141

#### **Approval date**

2012-10-17, 1391/07/26

#### **Ethics committee reference number**

29/5/1/2735

## **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 premenstrual syndrome

#### **Timepoint**

2 months before the study, 2 months after the intervention

#### **Method of measurement**

Daily chart position

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group: placebo capsules 2 times a day (2 tablets every 12 hours) for 7 days prior to the first day of the menstrual cycle

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Soft capsules containing 20 mg of essential oil and 2 times a day (every 12 hours 2 tablets) for 7 days prior to the first day of the menstrual cycle

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Kermani Dormitory, Isfahan University of Medical Sciences

##### **Full name of responsible person**

Marzieh Sodouri

##### **Street address**

Shiraz Gateways,Hezarjarib Street

##### **City**

Isfahan

## 2

### Recruitment center

**Name of recruitment center**

Milad Dormitory, Isfahan University of Medical Sciences

**Full name of responsible person**

Marzieh Sodouri

**Street address**

Shiraz Gateways, Hezarjarib Street

**City**

Isfahan

## 3

### Recruitment center

**Name of recruitment center**

Seyed Shohada Dormitory, Isfahan University of Medical Sciences

**Full name of responsible person**

Marzieh Sodouri

**Street address**

Motahari Street

**City**

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Kashan University of Medical Sciences

**Full name of responsible person**

Dr.Gholamali Hamidi

**Street address**

5th Kilometer Ghotbe Ravandi Bulv.

**City**

Kashan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Marzieh Sodouri

**Position**

Graduate student of nursing

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## Person responsible for scientific inquiries

### Contact

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Member of scientific mission

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## Person responsible for updating data

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**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*