

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of *Crocus Sativus L.*(saffron) on the intensity of PMS in the female university students

#### Protocol summary

##### Summary

Premenstrual syndrome is one of the most common health problems in women, affecting 20-40% of women in reproductive age. All the medicines prescribed for eliminating the intensity of premenstrual syndrome have some adverse effects. Therefore, this research is aimed to determine the effect of *Crocus Sativus L.* (saffron) on the intensity of PMS in the female university students resident in Lorestan University of Medical Sciences dormitories. This research is a randomized controlled trial on 88 students resident in dormitory with the age of 18-35 years, regular menstrual cycles, and experience of PMS symptoms. We will assign our subjects to receive capsules of *C.Sativus*, 30 mg/day (15mg, twice a day) or placebo (twice a day) for two menstrual cycles. Severity of symptoms will be compared between groups through DASS21 criteria and premenstrual assessment form.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138807292618N1**

Registration date: **2010-02-05, 1388/11/16**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2010-02-05, 1388/11/16

##### Registrant information

###### Name

Soheila Pirdadeh Beiranvand

###### Name of organization / entity

Lorestan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 66 1322 9095

##### Email address

s.pirdadeh@lums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Lorestan University of Medical Sciences

##### Expected recruitment start date

2010-04-21, 1389/02/01

##### Expected recruitment end date

2010-10-23, 1389/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of *Crocus Sativus L.*(saffron) on the intensity of PMS in the female university students

##### Public title

The effect of *Crocus Sativus L.*(saffron) on the intensity of PMS in the female university students

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age 18-35 years, residence in dormitory, having regular menstrual cycles, experience of PMS symptoms. Exclusion criteria: pregnancy, lactation, menstrual cycle irregularity, medical disease, hormonal method of contraception

##### Age

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

##### Gender

Female

##### Phase

1

## Groups that have been masked

No information

## Sample size

Target sample size: 88

## 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

Deputy of Research and Information Technology

#### Street address

Razi st, Enghelab Ave, Khorramabad, Lorestan, Iran

#### City

khorrabad

#### Postal code

6814989468

### Approval date

empty

### Ethics committee reference number

200/16172

## 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

Intensity of the premenstrual syndrome

### Timepoint

daily

### Method of measurement

premenstrual assessment form

## Secondary outcomes

empty

## Intervention groups

1

### Description

C.Sativus capsule, 30 mg/day (15 mg, twice a day) for 8 weeks

### Category

Treatment - Drugs

2

### Description

Placebo capsule (twice a day) for 8 weeks

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Lorestan University of Medical Sciences dormitories

#### Full name of responsible person

Soheila Pirdadeh Beiranvand

#### Street address

Department of midwifery, faculty of nursing and midwifery, Pardis Medical Campus, Kamalvand, Khorramabad, Lorestan, Iran

#### City

Khorramabad

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Deputy of Research and Information Technology

#### Full name of responsible person

Soheila Pirdadeh Beiranvand

#### Street address

Razi st, Enghelab Avenue, Khorramabad, Lorestan, Iran

#### City

Khorramabad

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Deputy of Research and Information Technology

### 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**

Lorestan Unuversity of Medical Sciences

**Full name of responsible person**

Soheila Pirdadeh Beiranvand

**Position**

MS. of midwifery

**Other areas of specialty/work****Street address**

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**City**

Khorramabad

**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*