

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**

Department of midwifery, faculty of nursing and midwifery, pardis medical campus, kamalvand, Khorramabad, Lorestan, Iran

City

Khorramabad

Postal code

381351698

Phone

+98 66 1322 9095

Fax

+98 66 1620 0140

Email

kimia_n72@yahoo.coms.pirdadeh@lums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Lorestan University of Medical Sciences

Full name of responsible person

Soheila Pirdadeh Beiranvand

Position

MS. of midwifery

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

Department of midwifery, faculty of nursing and midwifery, pardis medical campus, kamalvand, Khorramabad, Lorestan, Iran

City

Khorramabad

Postal code

381351698

Phone

+98 66 1322 9095

Fax

+98 66 1620 0140

Email

kimia_n72@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Lorestan University of Medical Sciences

Full name of responsible person

Soheila Pirdadeh Beiranvand

Position

MS. of midwifery

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

Department of midwifery, faculty of nursing and midwifery, pardis medical campus, kamalvand, Khorramabad, Lorestan, Iran

City

Khorramabad

Postal code

381351698

Phone

+98 66 1322 9095

Fax

+98 66 1620 0140

Email

kimia_n72@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