Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity
Lorestan University of Medical Sciences
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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

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khorramabad

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

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Sponsors / Funding sources

1

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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
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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