

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the effect of Saffron and Fluoxetine in treatment women that have Premenstrual Syndrome

Protocol summary

Summary

The goal of this study is to reduce the Premenstrual syndrome by using Saffron causing less side effects than Fluoxetine. This study was a double-blind (Phase 3) (none of the patients, researchers and analysts was aware of the contents of the capsules). that was performed on women that working in health center and their relatives. 164 women with informed consent and Premenstrual Syndrome (Based on the previous menstrual cycle and the Hamilton Test) were selected and randomly allocated in 2 groups. each group consisted of 82 women. One group received treatment with fluoxetine and one group with saffron. Cuses were treatment for 2 months. They used a capsule daily from 14 to 28 cycles. they completed the checklist Includes: Mastalgia, Abdominal Pain, Abdominal Bloat, Depression, Anxiety in 5 days later. inclusion criteria is informed consent, Eighteen to forty years, regular Menstrual Periods(35-21 days), Normal cycle (10-3 day) and Exclusion criteria is Underlying disease.

General information

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT2017061233202N2**

Registration date: **2017-09-08, 1396/06/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-08, 1396/06/17

Registrant information

Name

Atefeh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 9180

Email address

a.asadi.mm.1384@gmail.com

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Saffron and Fluoxetine in treatment women that have Premenstrual Syndrome

Public title

Effect of Saffrons in Premenstrual Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: informed consent; Eighteen to forty years; regular Menstrual Periods(35-21 days); Normal cycle (10-3 day); Physical and Mental health; The absence of anemia in the past three months ; Having one or more Symptoms of Premenstrual Syndrome in 2 consecutive cycles; no Pregnancy intention. Exclusion criteria: Underlying disease; Taking other drugs

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study was a double-blinded study, the researcher, analyst, and recipients were not aware of the contents of the capsule. Only the doctor in charge is aware of the contents of the capsule (with the numbered code on the package of the first and second capsule).

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Assadabadi Street

City

Sabzevar

Postal code

Approval date

2017-04-10, 1396/01/21

Ethics committee reference number

(IR.MEDSAB.REC.1395.148)

Health conditions studied

1

Description of health condition studied

Premenstrual Syndrome

ICD-10 code

N94

ICD-10 code description

Unspecified condition associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

Mastalgia

Timepoint

From 14 to 28 cycles are recorded on a daily basis

Method of measurement

Vigal Score

2

Description

Abdominal Pain

Timepoint

From 14 to 28 cycles are recorded on a daily basis

Method of measurement

Vigal Score

3

Description

Abdominal Bloat

Timepoint

From 14 to 28 cycles are recorded on a daily basis

Method of measurement

waist size

4

Description

Depression

Timepoint

From 14 to 28 cycles are recorded on a daily basis

Method of measurement

Test Depression Beck

5

Description

Anxiety

Timepoint

From 14 to 28 cycles are recorded on a daily basis

Method of measurement

Test anxiety Beck

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: saffron, self-made capsule 30 mg, oral, once a day from fourteen to twenty-eight day menstrual cycle for two months.

Category

Treatment - Drugs

2

Description

Control groups: fluoxetine, capsule 20 mg, oral, once a day from fourteen to twenty-eight day menstrual cycle for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Health Sabzevar

Full name of responsible person

Atefeh Asadi

Street address

Department of Health, Talghani Street, Sabzevar

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Mohammadzadeh

Street address

University Compound ; Unity Road Town

City

Sabzevar

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, Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Atefeh Asadi

Position

Health Department of Laboratory Medicine , Sabzevar

Other areas of specialty/work

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Full name of responsible person

Atefeh Aasadi

Position

General Practitioner

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

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Mohammad Nematshahy

Position

Anesthesiologist

Other areas of specialty/work

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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