

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison the effectiveness and side effects of three drugs- escitalopram, fluoxetine and vitagnus- in premenstrual dysphoric disorder

Protocol summary

Study aim

To assess the effectiveness, safety and side effects of three drugs- escitalopram, fluoxetine and vitagnus- in premenstrual dysphoric disorder

Design

Parallel groups randomized clinical trial with control group

Settings and conduct

In this randomized clinical trial 75 premenstrual dysphoric disorder patients whose disease will be confirmed by the study psychiatrist, based on diagnostic criteria of psychiatric disorders will be allocated randomly in two intervention groups and one control group. These patients will be examined at the end of the first, second and the third month of intervention and the effectiveness and safety of prescribed drugs will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmed diagnosis of premenstrual dysphoric disorder; To have regular menstrual periods; Assignment the informed consent form of the study
Exclusion criteria: Polycystic ovarian disease; Serious psychiatric disorders; and Breast feeding

Intervention groups

Intervention group 1: Escitalopram manufactured in Abidi's Pharmaceutical Company 10 milligram per day for three months; Intervention group 2: Vitagnus tablets manufactured in Poursina Pharmaceutical Company 20 milligram per day for three months; Control group: Fluoxetine manufactured in Abidi's Pharmaceutical Company 20 milligram per day for three months

Main outcome variables

The severity of premenstrual symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150630022991N13**

Registration date: **2018-10-12, 1397/07/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-12, 1397/07/20**

Update count: **0**

Registration date

2018-10-12, 1397/07/20

Registrant information

Name

Sussan Moudi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 5683

Email address

sussan.mouodi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness and side effects of three drugs- escitalopram, fluoxetine and vitagnus- in premenstrual dysphoric disorder

Public title

Escitalopram, fluoxetine and vitagnus in premenstrual dysphoric disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed diagnosis of premenstrual dysphoric disorder
To have regular menstrual periods
Assignment the informed consent form of the study

Exclusion criteria:

Polycystic ovarian disease
Irregular menstrual periods
Psychiatric disorders: dementia, psychosis, mental retardation, opium or psychoactive drugs abuse and high mood
Breast feeding

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

Randomization description

In order to random allocation of patients into the three groups of citalopram, fluoxetine and vitagnus, block randomization will be conducted. The free website of www.randomization.com is used to provide the sequence of allocation. The resulting sequence is written in separate sheets and placed in closed envelopes. These will be delivered to the chief researcher to conduct the study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Avenue, Babol

City

Babol

Province

Mazandaran

Postal code

4136747176

Approval date

2018-07-08, 1397/04/17

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.093

Health conditions studied

1

Description of health condition studied

Premenstrual dysphoric disorder

ICD-10 code

F38.8

ICD-10 code description

Other specified mood [affective] disorders

Primary outcomes

1

Description

The severity of premenstrual symptoms

Timepoint

At baseline (before initiation of the intervention) and at the end of the first, second and third months after the intervention

Method of measurement

Premenstrual Syndrome Diary (PMSD) questionnaire

Secondary outcomes

1

Description

The presence of psychologic symptoms

Timepoint

Before intervention and at the end of the third month after intervention

Method of measurement

Revised 90- Scale Symptom Checklist (SCL-90-R)

Intervention groups

1

Description

Intervention group 1: Escitalopram manufactured in Abidi's Pharmaceutical Company 10 milligram per day for three months

Category

Treatment - Drugs

2

Description

Intervention group 2: Vitagnus tablets manufactured in Poursina Pharmaceutical Company 20 milligram per day for three months

Category

Treatment - Drugs

3

Description

Control group: Fluoxetine manufactured in Abidi's Pharmaceutical Company 20 milligram per day for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Yahyanejad Hospital

Full name of responsible person

Sussan Moudi, MD

Street address

Shahid Yahyanejad Hospital, Modarres Avenue, Babol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi, PhD

Street address

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rezaghadimi@yahoo.com

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

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi

Position

Associate professor of psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Department of Psychiatry, Shahid Yahyanejad Hospital, Babol, Iran

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi

Position

Associate professor of psychiatry

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

Data associated with the study can be shared potentially
when the study population are unidentifiable.

When the data will become available and for how long

After publication of the final report

To whom data/document is available

Researchers in universities and academic organizations

Under which criteria data/document could be used

To cite to this study in future researches

From where data/document is obtainable

Sussan Moudi with email address

sussan.mouodi@gmail.com

What processes are involved for a request to access data/document

Within a maximum time of one month after receipt of the
request email, the response will be answered.

Comments