

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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		Babol University of Medical Sciences, Ganjafrooz Avenue, Babol	
Public title	Escitalopram, fluoxetine and vitagnus in premenstrual dysphoric disorder	City	Babol
Purpose	Treatment	Province	Mazandaran
Inclusion/Exclusion criteria		Postal code	4136747176
Inclusion criteria:	Confirmed diagnosis of premenstrual dysphoric disorder To have regular menstrual periods Assignment the informed consent form of the study	Approval date	2018-07-08, 1397/04/17
Exclusion criteria:	Polycystic ovarian disease Irregular menstrual periods Psychiatric disorders: dementia, psychosis, mental retardation, opium or psychoactive drugs abuse and high mood Breast feeding	Ethics committee reference number	IR.MUBABOL.HRI.REC.1397.093
Age	No age limit	Health conditions studied	
Gender	Female	1	
Phase	2-3	Description of health condition studied	
Groups that have been masked	No information	Premenstrual dysphoric disorder	
Sample size	Target sample size: 75	ICD-10 code	
Randomization (investigator's opinion)	Randomized	F38.8	
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.	ICD-10 code description	
Blinding (investigator's opinion)	Not blinded	Other specified mood [affective] disorders	
Blinding description		Primary outcomes	
Placebo	Not used	1	
Assignment	Parallel	Description	
Other design features		The severity of premenstrual symptoms	
Secondary Ids		Timepoint	
empty		At baseline (before initiation of the intervention) and at the end of the first, second and third months after the intervention	
Ethics committees		Method of measurement	
1		Premenstrual Syndrome Diary (PMSD) questionnaire	
Ethics committee		Secondary outcomes	
Name of ethics committee		1	
Ethics committee of Babol University of Medical Sciences		Description	
Street address		The presence of psychological 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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Mazandaran

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4717641367

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+98 11 3236 8823

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dr.mouodi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi, PhD

Street address

Babol University of Medical Sciences, Ganjafrooz Avenue, Babol

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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

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

sussan.mouodi@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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Position

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

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi

Position

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Latest degree

Specialist

Other areas of specialty/work

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