

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of drug holiday method on sexual function in women treated with selective serotonin reuptake inhibitors other than fluoxetine: a randomized clinical trial compared with control group

Protocol summary

Study aim

The effectiveness of drug holiday method on sexual function in women treated with selective serotonin reuptake inhibitors other than fluoxetine: a randomized clinical trial compared with control group

Design

In this two arm parallel group randomized trial, random allocation will be used based on balance block randomization and by 4:1 blocks

Settings and conduct

Female married patients in maintenance phase of treatment with a Selective Serotonin Reuptake Inhibitor and suffering from sexual side effect referred to outpatient psychiatric clinics of Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

18-50 years old female married patients live with their husbands, in maintenance phase of treatment with a SSRI and suffering from sexual side effect will be included. Patients with sexual dysfunction before starting the medication, substance dependence and taking another medication with established sexual side effect currently will be excluded

Intervention groups

Drug holiday group won't use the SSRI in two days in every week. Control group continues the medication without any change in type and dosage of the medication

Main outcome variables

Sexual Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211027052886N1**

Registration date: **2022-03-07, 1400/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-07, 1400/12/16**

Update count: **0**

Registration date

2022-03-07, 1400/12/16

Registrant information

Name

shiva soraya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4452 5615

Email address

soraya.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-06, 1400/12/15

Expected recruitment end date

2023-06-19, 1402/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of drug holiday method on sexual function in women treated with selective serotonin reuptake inhibitors other than fluoxetine: a randomized clinical trial compared with control group

Public title

Drug holiday method on sexual function in women treated with selective serotonin reuptake inhibitors

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

woman Married lived with husband In maintenance phase of treatment with a SSRI Suffering from sexual side effect

Exclusion criteria:

Sexual dysfunction before starting the medication substance dependence and taking another medication with established sexual side effect currently

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Entry to the study will be based on a block table of random numbers based on quadruple blocks, and each time a person enters the study, the evaluator and his / her importer will be unaware of what group the next person will be in. At any time, during contact with another researcher who has a table of numbers, he will be informed about his entry into the control group or intervention.

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to Milad Tower, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-10-22, 1400/07/30

Ethics committee reference number

IR.IUMS.FMD.REC.1400.417

Health conditions studied**1****Description of health condition studied**

Sexual side effect with SSRIs

ICD-10 code

F19.981

ICD-10 code description

Other psychoactive substance use, unspecified with psychoactive substance-induced sexual dysfunction

Primary outcomes**1****Description**

Sexual function

Timepoint

Weeks: 0, 4, 8

Method of measurement

Female Sexual Health Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 25 female and married patients undergoing maintenance phase of standard care with one of the selective serotonin reuptake inhibitors, except fluoxetine, enter the study and intervention is that the patient does not take medication for eight weeks on Tuesdays and Fridays. Also, the mental health assessment of patients will be performed on the basis of questionnaire 28 public health questions (GHQ - 28) in the first two turns and the end of the study. The authentication and monitoring of sexual performance is performed by the women's sexual performance index (FSFI). This assessment is a pre - intervention before intervention for all participants, and then they are told to answer all questions of the questionnaire after 4 and then 8 weeks after the study. to increase the degree of participation of participants and higher accuracy of information, every week by the researcher is called on by the researcher and is followed and followed by the pattern of the medication holiday, the incidence of duty, and the fulfillment of the questionnaire

Category

Treatment - Other

2

Description

Control group: 25 female and married patients undergoing maintenance phase of standard care with one of the selective serotonin reuptake inhibitors, except fluoxetine, are studied in the group of control and continue the drug without altering the type and dose of medicine. Also, the mental health assessment of patients will be performed on the basis of questionnaire 28 public health questions (GHQ - 28) in the first two turns and the end of the study. The authentication and monitoring of sexual performance is performed by the women's sexual performance index (FSFI). This assessment is a pre-intervention before intervention for all participants, and then they are told to answer all questions of the questionnaire after 4 and then 8 weeks after the study. to increase the degree of participation of participants and higher accuracy of information, every week by the researcher is called on by the researcher and is followed and followed by the pattern of the medication holiday, the incidence of duty, and the fulfillment of the questionnaire

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Psychiatric Hospital

Full name of responsible person

Dr shiva soraya

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Tehran-Karaj Highway 7 km

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

Dr Shiva Soraya

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hoseyn Keyvani

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

No

Title of funding source

Iran 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**

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Shiva Soraya

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data about main outcome of study will be published

When the data will become available and for how long

2024

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

For scientific goals

From where data/document is obtainable

dr.shivasoraya@gmail.com Dr Shiv Sorya

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

Sending an E-mail and reason of request

Comments