Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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)

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+98 21 4452 5615

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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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2

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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