Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of drug holiday method on sexual function in men 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 men 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
Male married patients in maintenance phase of treatment with a SSRI 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 male married patients live with their wife, 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
SSRIs

IRCT registration information
IRCT registration number: **IRCT20170123032145N6**
Registration date: **2021-10-25, 1400/08/03**
Registration timing: **prospective**

Last update: **2021-10-25, 1400/08/03**
Update count: **0**

Registration date
2021-10-25, 1400/08/03

Registrant information

Name
Mohammadreza Shalbafan

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6655 1665

Email address
shalbafan.mr@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-06, 1400/08/15

Expected recruitment end date
2023-03-20, 1401/12/29

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 men 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 men treated with selective serotonin reuptake inhibitors
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Married lived with wife 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
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks
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, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2021-05-16, 1400/02/26
Ethics committee reference number
IR.IUMS.FMD.REC.1400.130

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
Male Sexual Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Drug holiday group won`t use the SSRI in two days in every week.
Category
Treatment - Other

2

Description
Control group: Control group continues the medication without any change in type and dosage of the medication.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran Psychiatric Hospital
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Tehran-Karaj Highway 7 km
City
Tehran

Province
Tehran
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1398913151
Phone
+98 21 4450 3395
Email
Shalbafan.mr@iums.ac.ir
Web page address
http://iph.iums.ac.ir/

2

Recruitment center
Name of recruitment center
Tehran Psychiatric Institute
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue
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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
Street address
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1449614535
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mhrc@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Dr Mohammadreza Shalbafan
Proportion provided by this source
100
Public or private sector
Private
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 Mohammadreza Shalbafan
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

shalbafan.mr@iums.ac.ir Dr Mohammadreza Shalbafan

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

Sending an E-mail and reason of request

Comments