

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Shalbfafan

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1665

Email address

shalbfafan.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 Shalbfan

Street address

Tehran-Karaj Highway 7 km

City

Tehran

Province
Tehran
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1398913151
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+98 21 4450 3395
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Shalbafan.mr@iums.ac.ir
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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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Shalbafan.mr@iums.ac.ir

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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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 updating data

Contact

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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