

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of bupropion on the sexual function of patients with sexual side effects caused by SSRI use, a double-blind clinical trial

Protocol summary

Study aim

Investigating the effect of bupropion on the sexual function of patients with sexual side effects caused by SSRI use

Design

This double-blind clinical trial will be conducted in parallel on 60 patients consuming SSRIs and suffering from sexual disorders who are randomly divided into two equal groups. Block randomization method will be used for random allocation. The block size will be 4 and for this purpose 15 blocks with 4 subjects in each block will be used.

Settings and conduct

This study will be conducted as a clinical trial study with a control group on a total of 60 patients referred to Razi Hospital of Tabriz. In this study, the evaluator and the analyzer are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients under SSRI treatment for at least three consecutive months, having sexual dysfunction for at least the last two months, married and sexually active, Age range 15-55 years . Exclusion criteria: The presence of digestive problems such as severe nausea and vomiting and SSRI intolerance, The presence of any anatomical problem of the reproductive system, The existence of any severe or relatively severe hormonal disorder, Absence of pregnancy, Lack of breastfeeding and Non-participation in the study.

Intervention groups

Intervention group: after justifying the patients , 75 mg bupropion tablets are prescribed once a day during the study (8 weeks). Control group: after justifying the patients, only the prescribed treatment similar to the intervention group and without the use of bupropion is prescribed during the study (8 weeks).

Main outcome variables

Measuring sexual satisfaction; Measuring sexual performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151022024650N2**

Registration date: **2023-01-01, 1401/10/11**

Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**

Update count: **0**

Registration date

2023-01-01, 1401/10/11

Registrant information

Name

Sepideh Herizchi

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

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+98 41 3380 3353

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herizchis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of bupropion on the sexual function of patients with sexual side effects caused by SSRI use, a double-blind clinical trial

Public title

The effect of bupropion on the improvement of sexual side effects caused by SSRI use

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients under SSRI treatment for at least three consecutive months; having sexual dysfunction for at least the last two months; married and sexually active; Age range 15-55 years; stable vital signs.

Exclusion criteria:

The presence of digestive problems such as severe nausea and vomiting and SSRI intolerance; The presence of concurrent chronic liver or kidney disease; The presence of any anatomical problem of the reproductive system; The existence of any severe or relatively severe hormonal disorder; Absence of pregnancy; Lack of breastfeeding; Non-participation in the study.

Age

From **15 years** old to **55 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block randomization; Random unit: individual. Randomization tool: An online randomization website. Sequence building: using block randomization method with block size of 4. Concealing method: using closed and opaque envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, clinical evaluator and analyzer are blinded. The allocation of patients into two groups A and B is done by a qualified nurse who has no aware of the actions performed in the two groups. Clinical examination and outcome evaluation will be record by a qualified nurse without any information about the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

29 Bahman street., Tabriz., Iran

City

Tabriz

Province

East Azarbaijan

Postal code

۳۶۱۵۶۷۳۳۲۷

Approval date

2022-06-15, 1401/03/25

Ethics committee reference number

IR.TBZMED.REC.1401.274

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Measuring sexual satisfaction

Timepoint

Once a Month

Method of measurement

Hudson's Standardized Sexual Satisfaction Questionnaire (ISS)

2

Description

Measuring sexual performance

Timepoint

Once a Month

Method of measurement

Rozen Standardized Women's Sexual Performance Questionnaire (FSFI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after justifying the patients and providing the necessary training, 75 mg bupropion tablets are prescribed once a day during the study (8 weeks).

Category

Treatment - Drugs

2

Description

Control group: after justifying the patients and providing the necessary training, only the prescribed treatment similar to the intervention group and without the use of bupropion is prescribed during the study (8 weeks).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital., Tabriz., Iran

Full name of responsible person

Dr. Elham Ghasemi

Street address

29 Bahman street., Tabriz., Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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Azadi Blvd., Golgasht street.,

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Elham Ghasemi

Position

Resident of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Sepideh Harizchi Ghadim

Position

Associate professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Elham Ghasemi

Position

Resident of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

29 Bahman street., Tabriz., Iran

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available