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)
Phone
+98 41 3380 3353
Email address
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
City
Tabriz
Province
East Azarbaijan
Postal code
۳۶۱۵۶۷۳۳۲۷
Phone
+98 939 667 6405
Email
dr.egh92@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
Street address
Azadi Blvd., Golgasht street.,
City
Tabriz
Province
East Azarbaijan
Postal code
۳۶۱۵۶۷۳۳۲۷
Phone
+98 939 667 6405
Email
dr.egh92@gmail.com
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
Street address
29 Bahman street., Tabriz., Iran.
City
Tabriz
Province
East Azarbaijan
Postal code
۳۶۱۵۶۷۳۳۲۷
Phone
+98 939 667 6405
Email
dr.egh92@gmail.com

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

Street address
29 Bahman street., Tabriz., Iran
City
Tabriz
Province
East Azarbaijan
Postal code
۳۶۱۵۶۷۳۳۲۷
Phone
+98 939 667 6405
Email
herizchis@tbzmed.ac.ir

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
City
tabriz
Province
East Azarbaijan
Postal code
۳۶۱۵۶۷۳۳۲۷
Phone
+98 939 667 6405
Email
dr.egh92@gmail.com

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