Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Bupropion on sexual function of women with orgasmic disorder

Protocol summary

Study aim
Determine the effectiveness of bupropion on sexual function of women with orgasm disorders

Design
Clinical trial with parallel control group, double blinded and randomization.

Settings and conduct
In this study, women with orgasm disorders who are referred to the psychiatric clinic of the Khorshid's Hospital included in the study. Patients are divided into two groups of drug and placebo on the basis of block randomization. And the presenter, the patient, and the distributor of the drug, are not known to the patient's treatment. In this plan, the drug starts at a daily dose of 75 mg per day to the maximum dose of 300 mg/day. The control group will use placebo. Female sexual function score and its sub-scales were measured and recorded before, 2, 4, 6 and 8 weeks after the intervention in the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Reading and writing literacy Woman aged 18 to 50 years Having a sexual partner (husband) who has no sexual dysfunction The complaint of a global female orgasmic disorder Exclusion criteria: Dissatisfaction to continue participating in the study at any time Pregnancy during the study Couple's death or divorce during the study

Intervention groups
In the intervention group, a dose of 75 mg per day is started daily, and the treatment is continued according to the effect of the symptoms on a weekly basis, to a maximum dose of 300 mg per day and the second group will be given placebo instead of bupropion.

Main outcome variables
Female sexual function score and its sub-scales as a primary outcome by Persian version of the validated and endorsed female sexual function index and sexual satisfaction of persons by the Larsson Sexual Satisfaction Questionnaire before, 2, 4, 6, 8 weeks after intervention in both intervention and control groups will be record and measure.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090801002266N9**
Registration date: **2018-12-07, 1397/09/16**
Registration timing: **prospective**

Last update: **2018-12-07, 1397/09/16**
Update count: **0**

Registration date
2018-12-07, 1397/09/16

Registrant information

Name
Gholamreza Kheirabadi
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of Bupropion on sexual function of women with orgasmic disorder

Public title
Efficacy of Bupropion on sexual function of women with orgasmic disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Reading and writing literacy Woman aged 18 to 50 years Negative pregnancy test and no action for pregnancy during the intervention Having a sexual partner (husband) who has no sexual dysfunction (spouse sexual intercourse is rejected by clinical interview). She is in a marital relationship for at least six months, not considering divorce or separation, and alternately having sex with her husband. The lack of active psychiatric illness Not having sexual desire and pain disorder (disparonius and vaginismus) simultaneously Non-menopause (natural or surgical) Not having a history of primary and secondary infertility The complaint of a global female orgasmic disorder should be as follows: a) Frequency of orgasms during sexual intercourse in less than 50% of sexual relationships. b) There is a disorder for at least 6 months. c) Has reached orgasm at least 3 times in the last 6 months. Not having anxiety disorder at the same time (Beck anxiety disorder score less than 10). Not having depressive disorder at the same time (Beck Depression Questionnaire score is less than 10). Not having sexual and paraphilia disorders History of seizure or head injury No substance abuse or alcohol abuse over the past year Non-use of psychiatric drugs and any drugs that affect sexual function (chronic use of opioids beta blockers, alpha-adrenergic drugs, psychotropic drugs) Failure to receive synchronous psychological intervention

Exclusion criteria:
Dissatisfaction to continue participating in the study at any time Pregnancy during the study Couple's death or divorce during the study

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using a random number table for people with obsessive-compulsive disorder. The random numbers and numbers are extracted by the computer and for allocation concealment unique code will be used

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients do not know the type of drug they are taking and the drug is given to them in separate packages and the shape and color of the drug are not recognizable. The person with whom he or she is affiliated as a health care provider will not be provided with information about the patient's drug use.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of isfahan university of medical science

Street address
Behavioal science research center, noor hospital, ostandari street, isfahan, iran

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Isfahan

Province
Isfehan

Postal code
8145831451

Approval date
2018-03-01, 1396/12/10

Ethics committee reference number
IR.MUI.REC.1396.3.992

Health conditions studied

1

Description of health condition studied
Orgasmic disorder

ICD-10 code
F52.31

ICD-10 code description
Female orgasmic disorder

Primary outcomes

1

Description
changes in female sexual function score base on the female sexual function index

Timepoint
Before intervention 2, 4, 6, 8 weeks after intervention

Method of measurement
Female sex function index questionnaire

2

Description
Changes in female sexual satisfaction
Timepoint
Before intervention 2, 4, 6, 8 weeks after intervention
Method of measurement
Larsson Women's Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Bupropion is given at a daily dose of 75 mg (half a tablet of 150 mg) per day, and the treatment is continued according to the effect of the symptoms on a weekly basis, to a maximum dose of 300 mg per day (two The pill number is 150 mg)
Category
Treatment - Drugs

2

Description
Control group: In this group, patients receive placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
khorshid hospital
Full name of responsible person
Gholam Reza Kheirabadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr Gholam Reza Kheirabadi
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Psychiatrist/ Assistant Professor
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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
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data will be available.
When the data will become available and for how long
The start of the access time is immediately after the relevant article is publish.
To whom data/document is available
All people can access the data.
Under which criteria data/document could be used
All analyzes needed can be done on data, and all individuals can apply for data
From where data/document is obtainable
Applicants can contact the phone number 09138325471 to receive the data
What processes are involved for a request to access data/document
The data will be available to the applicant as soon as possible.
Comments