

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

bupropion efficacy on sexual arousal and interest among female patient suffering multiple sclerosis

Protocol summary

Study aim

therapeutic efficacy of bupropion on sexual arousal and desire disorder in female patient with multiple sclerosis

Design

60 married female patient with MS diagnosis and sexual arousal and desire disorder according to DSM-V, enter the study. the patients are divided in to 2 group as case and control according to randomized block.

Settings and conduct

60 patients who are visited in Kashani hospital of Isfahan enter the study after receiving informed consent. drug and placebo are given to patients in identical package. patients and the person who follow up them have no information about the drug type.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1-ability to read and write 2-age between 18-50 3-have a contraception method and no plan for pregnancy during intervention 4-a marital relationship for at least six months, not considering divorce or separation, and alternately having sex with her husband 5-diagnosis of sexual arousal and desire disorder according to FSFI criteria exclusion criteria: 1- her husband has a sexual disorder 2-active psychiatric illness (except depression) 3- having sexual pain disorder, sexual identity disorder and paraphilia simultaneously 4-menopause 5-primary or secondary infertility 6-history of seizure or head injury 7-alcohol or substance abuse in previous year 8-taking psychiatric drugs or any medication which affect sexual function 9- receiving concomitant psychological intervention

Intervention groups

the trial group receive bupropion with maximum dose of 300 mg per day and control group receive an identical placebo.

Main outcome variables

sexual function, intimacy and sexual function, fatigue, depression, sexual desire, sexual arousal, vaginal lubrication, orgasm, sexual satisfaction, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120302009188N2**

Registration date: **2020-02-15, 1398/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-15, 1398/11/26**

Update count: **0**

Registration date

2020-02-15, 1398/11/26

Registrant information

Name

Majid Barekatain

Name of organization / entity

Isfahan university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 2475

Email address

barekatain@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-21, 1398/07/29

Expected recruitment end date

2020-02-18, 1398/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

bupropion efficacy on sexual arousal and interest among female patient suffering multiple sclerosis

Public title

bupropion therapy in multiple sclerosis patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ability to read and write age between 18-50 year old use of a contraception method and no planning for pregnancy being in sexual relation for at least 6 months and do not think about divorce or separation and have sexual intercourse with her partner routinely diagnosis of sexual arousal and interest disorder according to FSFI

Exclusion criteria:

having a partner with sexual disorder suffering from an acute psychiatric disorder (with the exception of depression) having sexual pain disorder (dyspareunia or vaginismus), gender identity disorder, paraphilia menopause having primary or secondary infertility history of convulsion or head injury substance or alcohol abuse in previous year taking psychiatric drug or any medication which affect sexual function receiving a psychotherapy simultaneously

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

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

the patients are divided in two groups of case and control according to block random allocation

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethic committee of Isfahan university of medical science

Street address

Behavioral science research center, noor hospital, ostandari street, isfahan, iran

City

Isfahan

Province

Isfahan

Postal code

8145831451

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.MUI.MED.REC.1398.124

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

sexual function rate in female sexual function index questionnaire

Timepoint

measurement of female sexual function index at the beginning of the study (before intervention) and 4,8 weeks after taking Bupropion

Method of measurement

female sexual function index questionnaire

Secondary outcomes

1

Description

fatigue severity

Timepoint

measurement of fatigue severity at the beginning of the study and 4,8 weeks after taking Bupropion

Method of measurement

fatigue severity scale

2

Description

beck depression scale

Timepoint

measurement of depression at the beginning of the study and 4,8 weeks after taking Bupropion

Method of measurement

beck depression inventory

Intervention groups

1

Description

Intervention group:bupropion tablets are formed in 2 dosage 75 and 150 mg.in this study therapy is started with 75 mg daily and according to patient response to the drug the dosage will be increased weekly to the maximum dosage of 150 mg twice daily. therapy last for 2 months.

Category

Treatment - Drugs

2

Description

Control group: instead of bupropion, the patients receive placebo.(tablets in same size,shape, color without effective substance, which will be delivered in paper bag) use instruction is the same as intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

kashani hospital

Full name of responsible person

majid barekatin

Street address

Behavioral science research center, noor hospital, ostandari street, isfahan, iran

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2475

Email

barekatin@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Shaghayegh haghdoost

Street address

hezar jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3793 2273

Email

info@mui.ac.ir

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

Majid barekatin

Position

full professor of psychiatry

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Ostandari street

City

Isfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3222 2475

Email

barekatin@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Majid barekatin

Position

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Latest degree

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Other areas of specialty/work

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Ostandari Ave.

City

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Province

Isfahan

Postal code

8174673441

Phone

+98 31 3222 2475

Email

barekatin@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

majid barekatin

Position

full professor of psychiatry

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Other areas of specialty/work

Psychiatrics

Street address

Behavioral Sciences Research Center, Khorshid hospital

City

isfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3222 2475

Email

barekatin@med.mui.ac.ir

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 09173877382 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