# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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-recieving 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)

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**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(disparunia 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**
Behavioal science research center, noor hospital, ostandari street, isfahan, iran

**City**
Isfahan

**Province**
Isfehan

**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 barekatain
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Behavioal science research center, noor hospital, ostandari street, isfahan, iran
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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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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 barekatain
**Position**
full professor of psychiatry
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Psychiatrics
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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 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**