# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Efficacy and safety evaluation of bupropion on sexual dysfunction in female patients with multiple sclerosis - a double blind randomized clinical trial

## Protocol summary

**Study aim**

Evaluation of efficacy and safety of bupropion on sexual dysfunction in female patients with multiple sclerosis

**Design**

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 64 patients. Block permutated randomization method has been used for randomization.

**Settings and conduct**

The study site of MS Clinic is Bu Ali Sina Hospital in Sari. The study was double-blind and participants and researchers were blinded. The questionnaires will be filled in at the beginning of the study, at the end of the sixth week and at the end of the twelfth week.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Adult women over 18 years, The duration of MS is more than six months, Having been sexually active for the past six months, No known acute mental disorder, Husband monogamy, Exclusion criteria: The study included moderate to severe depression using the HADS questionnaire (score 11 and above), Consumption of silicotropic drugs and benzodiazepines and SSRIs during the study, Known acute mental disorder, Pregnancy or breastfeeding Environmental problems of the genitourinary system lead to sexual dysfunction Facing severe crises such as the death of loved ones during the last six months Withdrawal from study and incomplete answers to the questionnaires so that more than 20% of the questions in each questionnaire are unanswered. History of seizures, History of bulimia and anorexia.

**Intervention groups**

The intervention group received bupropion tablets 75 mg daily for the first week and then 75 mg morning and night until the end of the study period, and the control group received placebo instead of bupropion while maintaining all the conditions of the intervention group. The duration of the study is 12 weeks.

**Main outcome variables**

Quality of Life; Intimacy and sexual activity; Side effects; Fatigue; Sphincter disorder; Anxiety and depression;

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20140105016087N2**
Registration date: **2021-04-23, 1400/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-23, 1400/02/03**
Update count: **0**

**Registration date**

2021-04-23, 1400/02/03

**Registrant information**

**Name**

Seyed Mohammad Baghbanian

**Name of organization / entity**

Mazandaran faculty of medicine

**Country**

Iran (Islamic Republic of)

**Phone**

+98 15 1223 3018

**Email address**

sm.baghbanian@mazums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-04-22, 1400/02/02

**Expected recruitment end date**

2021-12-23, 1400/10/02

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Efficacy and safety evaluation of bupropion on sexual dysfunction in female patients with multiple sclerosis - a double blind randomized clinical trial

**Public title**
The effect of bupropion on impotence in female MS patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Adult women over 18 years The duration of MS is more than six months Having sexual activity in the last six months Not known to have an acute mental disorder Husband monogamy
**Exclusion criteria:**
Moderate to severe depression with HADS questionnaire (score 11 and above) Consumption of silicotropic drugs and benzodiazepines and SSRIs during the study Known for acute mental disorder Pregnancy or breastfeeding Peripheral problems of the genitourinary system lead to sexual dysfunction Facing severe crises such as the death of loved ones during the last six months Withdrawal from study and incomplete answers to the questionnaires so that more than 20% of the questions in each questionnaire are unanswered. History of seizures History of bulimia and anorexia
**Age**
From **18 years** old
**Gender**
Female

**Phase**
2-3
**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **64**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients who are eligible for the study are divided into two groups A and group B using block permutated randomization. Blocking is usually used to balance the number of samples assigned to each of the studied groups. In this study, quadruple blocks including two people from group A and two people from group B are considered and the selection of blocks is considered. It will be in random numbers.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Participants, the principal investigator, the data collector, and those evaluating the outcome are blinded in the study.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethical committee of Mazandaran University of Medical Sciences
**Street address**
Vice chancellor of Booalisina Hospital- Pasdaran Blvd.
**City**
Sari
**Province**
Mazandaran
**Postal code**
4815838477
**Approval date**
2021-01-24, 1399/11/05
**Ethics committee reference number**
IR.MAZUMS..REC.1399.8189

## Health conditions studied

### 1

**Description of health condition studied**
Multiple Sclerosis
**ICD-10 code**
G35
**ICD-10 code description**
Multiple sclerosis

### 2

**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**
Intimacy and sexual activity in MSISQ 19 questionnaire
**Timepoint**

The beginning of the study, the sixth week and the twelfth week

**Method of measurement**

MSISQ 19 questionnaire

**2**

**Description**

Percentage of people with a depression score of less than 11 on the HADS questionnaire

**Timepoint**

The beginning of the study

**Method of measurement**

HADS questionnaire

## Secondary outcomes

**1**

**Description**

Multiple Sclerosis Quality Of Life

**Timepoint**

The beginning of the study-End of study

**Method of measurement**

(MSQOL-54)

**2**

**Description**

Fatigue

**Timepoint**

The beginning of the study

**Method of measurement**

The Multidimensional Fatigue Inventory

**3**

**Description**

Sphincter disorders

**Timepoint**

The beginning of the study

**Method of measurement**

Sphincter Disorder Questionnaire

## Intervention groups

**1**

**Description**

Intervention group:

**Category**

Treatment - Drugs

**2**

**Description**

Control group:

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Booalisina hospital

**Full name of responsible person**

Seyed Mohammad Baghbanian

**Street address**

Pasdaran Blvd

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815838477

**Phone**

+98 11 3334 3348

**Email**

sm.baghbanian@mazums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

معاون تحقیقات و فناوری دانشگاه علوم پزشکی مازندران

**Street address**

Moalem Square. Moalem St.

**City**

Sari

**Province**

Mazandaran

**Postal code**

۴۸۱۵۷۳۳۹۷۱

**Phone**

+98 11 3325 7230

**Email**

pajoheshi@mazums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Mazandaran 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**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Seyed Mohammad Baghbanian

**Position**
Assistant professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Multiple sclerosis fellowship

**Street address**
Pasdaran Blvd. Booalisina hospital

**City**
Sari

**Province**
Mazandaran

**Postal code**
4815838477

**Phone**
+98 11 3334 3348

**Email**
sm.baghbanian@mazums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Seyed Mohammad Baghbanian

**Position**
Assistant Professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Multiple sclerosis fellowship

**Street address**
Pasdaran Blvd.

**City**
Sari

**Province**
Mazandaran

**Postal code**
4815838477

**Phone**
+98 11 3334 3348

**Email**
sm.baghbanian@mazums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Seyed Mohammad Baghbanian

**Position**
Assistant professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Multiple sclerosis

**Street address**
Pasdaran Bvld. Booalisina hospital

**City**
Sari

**Province**
Mazandaran

**Postal code**
4815838477

**Phone**
+98 11 3334 3348

**Email**
sm.baghbanian@mazums.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 is potentially shareable after unidentified individuals

**When the data will become available and for how long**
Access period starts 6 months after the results are published

**To whom data/document is available**
It will be available to researchers working in academic and scientific institutions and to people working in the pharmaceutical industry

**Under which criteria data/document could be used**
Any analysis of unidentified personal data is allowed. Applicants must apply through formal academic channels.

**From where data/document is obtainable**
MS clinic - Booalisina hospital - Pasdaran Bvld. sm.baghbanian@mazums.ac.ir

**What processes are involved for a request to access data/document**
The applicant is required to state his / her purpose of access to the documents by e-mail and, if he / she is to be used in the research work, to inform the proposal and the code of ethics received by e-mail.

**Comments**