Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 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)

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+98 15 1223 3018

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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

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Pasdaran Blvd

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4815838477

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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.

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Postal code

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+98 11 3325 7230

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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

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Pasdaran Blvd. Booalisina hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Seyed Mohammad Baghbanian

Position
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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 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