# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Investigating the effect and side effects of bupropion on fatigue, disability and quality of life of multiple sclerosis patients

## Protocol summary

**Study aim**
Investigating the effect and side effects of bupropion on fatigue, disability and quality of life of multiple sclerosis patients

**Design**
A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 100 patients. Blocks of four will be used for randomization.

**Settings and conduct**
This study is a randomized clinical trial (blocks of four), double blind (participants and results analyzer), with parallel groups, without a control group and with the participation of 80 patients with multiple sclerosis referred to Imam Reza Hospital (Tabriz). will be done. In this study, the effects and complications of bupropion in patients will be investigated.

**Participants/Inclusion and exclusion criteria**
The most important criteria for entering the study include a definitive diagnosis of multiple sclerosis based on the MacDonald criteria, 2017 version, and an EDSS value of less than four, and the most important exclusion criteria include: the use of drugs that have a reducing or intensifying effect on fatigue, such as dalfampridine, modafinil, anti Depressants and other psychiatric drugs and the use of other auxiliary methods such as herbal medicines, antidepressants, yoga, unnecessary supplements, addiction or drug use.

**Intervention groups**
In this study, patients who will refer to the doctor due to multiple sclerosis will undergo intervention. Patients will be randomly divided into two groups. For one group, along with routine treatments, Bupropion drug will be prescribed and for another group, placebo drug will be prescribed along with routine drugs, and finally, the level of fatigue and quality of life will be compared in them.

**Main outcome variables**
Quality of life

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190325043107N48**
Registration date: **2024-08-10, 1403/05/20**
Registration timing: **prospective**

Last update: **2024-08-10, 1403/05/20**
Update count: **0**

**Registration date**
2024-08-10, 1403/05/20

**Registrant information**

**Name**
Mehdi Khanbabayi Gol

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-10-21, 1403/07/30

**Expected recruitment end date**
2025-03-18, 1403/12/28

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Investigating the effect and side effects of bupropion on fatigue, disability and quality of life of multiple sclerosis patients

**Public title**
Investigating the effects and side effects of bupropion in multiple sclerosis patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Definitive diagnosis of multiple sclerosis based on MacDonald criteria 2017 version EDSS value smaller than four
**Exclusion criteria:**
Taking drugs that have a reducing or intensifying effect on fatigue, such as dalfampridine, modafinil, antidepressants and other psychiatric drugs. Using other auxiliary methods such as herbal medicines, antidepressants, yoga, unnecessary supplements, addiction or drug use
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

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

- Participant
- Data analyser

**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they will divid into two intervention groups (group A) and control group (group B).
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The thesis results analyst who will analyze the expected result and also the participants will be unaware of the type of procedure performed and will be blind during the study; Therefore, this study will be conducted in a double-blind manner. Since the participants will be unaware of the type of technique used, in this study they will not know what type of technique will be used in other patients.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Tabriz University of Medical Sciences
**Street address**
Imam Reza Hospital, Azadi Ave
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5165665631
**Approval date**
2024-07-21, 1403/04/31
**Ethics committee reference number**
IR.TBZMED.REC.1403.338

## Health conditions studied

### 1

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

## Primary outcomes

### 1

**Description**
Quality of life
**Timepoint**
Once every month for six months
**Method of measurement**
McGill Quality of Life Questionnaire

### 2

**Description**
Fatigue
**Timepoint**
Once every month for six months
**Method of measurement**
Physical examination and asking the patient himself

**3**

**Description**
Disability
**Timepoint**
Once every month for six months
**Method of measurement**
Physical examination and asking the patient himself

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: The patients of this group will be prescribed bupropion (150 mg/extended release product of Obidi company) once a day for six months in addition to routine treatments, and finally the quality of life (measured using the McGill Quality of Life Questionnaire) and fatigue. and disability (measurement in the form of physical examination and questions from the patient himself) will be measured once a month for six months.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Patients of this group will be prescribed placebo (the same color, shape and size of the intervention group pills) once a day for six months in addition to the routine treatments, and finally the quality of life (measured with the help of the McGill Quality of Life Questionnaire) ) and fatigue and disability (measured by physical examination and asking the patient himself) will be measured once a month for six months.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
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## Sponsors / Funding sources

**1**

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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**
Tabriz 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**
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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)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available