Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Effect of Bupropion versus placebo on the management of fatigue caused by multiple sclerosis: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of Bupropion versus placebo on the management of fatigue caused by multiple sclerosis

Design
This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Besat Hospital in Hamadan city on 46 eligible patients with multiple sclerosis. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 65 years Multiple sclerosis Exclusion criteria: Pregnancy or breastfeeding Hepatic or renal failure A history of convulsion or epilepsy A history of alcohol use A history of attempting suicide

Intervention groups
Intervention group: Routine Treatment plus Bupropion tablet 75 mg daily for 3 days then twice a day for 60 days Control group: Routine Treatment plus placebo tablet (starch) daily for 3 days then twice a day for 60 days

Main outcome variables
Primary outcome: Fatigue, quality of life, disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N465**
Registration date: **2023-03-09, 1401/12/18**
Registration timing: **prospective**

Last update: **2023-03-09, 1401/12/18**
Update count: **0**

Registration date
2023-03-09, 1401/12/18

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Bupropion versus placebo on the management of fatigue caused by multiple sclerosis: a double-blind randomized clinical trial

Public title
Effect of Bupropion versus placebo on the management of fatigue caused by multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Multiple sclerosis

Exclusion criteria:

Pregnancy or breastfeeding Hepatic or renal failure A history of convulsion or epilepsy A history of alcohol use A history of attempting suicide

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-01-14, 1401/10/24

Ethics committee reference number

IR.UMSHA.REC.1401.891

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

Fatigue score

Timepoint

Before the intervention and one and two months after the intervention

Method of measurement

Using the Modified Fatigue Impact Scale (MFIS)

2

Description

Quality of life score

Timepoint

Before Intervention and two months after the intervention

Method of measurement

Using Multiple Sclerosis Quality of Life-54 Questionnaire (MSQOL-54)

3

Description

Disability score

Timepoint

Before the intervention and one and two months after the intervention

Method of measurement

using the Expanded Disability Status Scale (EDSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine Treatment plus Bupropion tablet 75 mg daily for 3 days then twice a day for 60 days
Category
Treatment - Drugs

2

Description
Control group: Routine Treatment plus placebo tablet (starch) daily for 3 days then twice a day for 60 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan city
Full name of responsible person
Shiva Tane
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
shivatnh3α@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Shiva Tane
Position
Medical Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
shivatnh3α@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Shahabodine Emami
Position
Clinical Pharmacologist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address

School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
sha_emami@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Jalal Poorolajal

Position
Professor of Epidemiology

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0090

Email
poorolajal@umsha.ac.ir

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