

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Lacosamide efficacy and safety on pain in patients with multiple sclerosis: A randomized double-blind clinical trial

#### Protocol summary

##### Study aim

Lacosamide efficacy and safety on pain in patients with multiple sclerosis : A randomized double-blind clinical trial

##### Design

Based on the randomization table (permuted block method in blocks of 4), patients are candidates to receive lacosamide or placebo for 12 weeks. All patients included in the study, who are 56 and placed in parallel groups, will receive a standard treatment regimen.

##### Settings and conduct

Patients with MS referred to the MS clinic of Bo Ali Sina Educational Center who meet the inclusion criteria and do not have the exclusion criteria are included in the study and are divided into two groups according to the randomization table and are evaluated for 12 weeks. The treating doctor, the patient and the evaluator are unaware of the type of therapeutic intervention.

##### Participants/Inclusion and exclusion criteria

Adults over 18 years of age and suffering from MS with moderate to high MS pain complaints are included in the study. Pregnant and lactating women, people with severe depression or suicidal thoughts, thyroid disorders, severe anemia, cerebral ischemia or cardiovascular disease, kidney failure, MS attack and corticosteroid pulse within the last month, drug abuse, psychotropic substances and alcohol , liver failure, cardiac arrhythmia or simultaneous use of drugs affecting heart rhythm and drugs affecting pain control, structural disorders affecting pain are excluded from the study.

##### Intervention groups

lacosamide 100 mg BD for the first week then 150 mg BD for second week after that 200 mg BD

##### Main outcome variables

Determining the effectiveness of lacosamide in reducing the intensity of pain caused by MS in patients with BPI and NPSI scales. Determining the overall improvement rate of MS patients after taking lacosamide based on (PGIC). Determining the improvement of function and

quality of life of patients with MS after taking lacosamide based on (SF\_36)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190804044429N8**

Registration date: **2022-09-04, 1401/06/13**

Registration timing: **prospective**

Last update: **2022-09-04, 1401/06/13**

Update count: **0**

##### Registration date

2022-09-04, 1401/06/13

##### Registrant information

##### Name

Monireh Ghazaeian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8863 6864

##### Email address

ghazaeianm@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Lacosamide efficacy and safety on pain in patients with multiple sclerosis: A randomized double\_blind clinical trial

**Public title**

Lacosamide efficacy and safety on pain in patients with multiple sclerosis: A randomized double\_blind clinical trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Adults over the age of 18 and suffering from MS with moderate to high MS pain complaint

**Exclusion criteria:**

Severe depression or suicidal thoughts  
Thyroid disorders  
Severe anemia (Hb<9g/dl)  
Breast feeding or pregnancy  
History of cerebral ischemia or cardiovascular disease  
Having kidney failure (creatinine clearance less than 30 ml/min)  
Existence of an MS attack during the past month  
Concomitant use of drugs effective in pain control during the last month  
History of abuse of drugs, psychotropic substances and alcohol  
History of liver failure  
History of cardiac arrhythmia or simultaneous use of drugs affecting heart rhythm  
Failure to receive corticosteroid pulse within a month before the starting of study  
Absence of a history of structural disorder affecting the occurrence of pain such as discopathy and other disease affecting the occurrence of neuropathic pain( diabetes, trigeminal neuralgia,...)

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **56**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random block method will be used to allocate the samples to two groups. Blocks will be considered as 4 blocks and in each block of 4 people, two people in the intervention group and two people in the control group will be selected. The selection of the order type in each group for each person will be done through second version of random allocation software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is double\_blind. Outcome evaluator and participant are blinded (double blind) and aware from grouping (intervention or placebo)

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mazandaran university of medical Sciences

**Street address**

Ibn Sina hospital, Pasdaran Blvd, Sari town

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816864193

**Approval date**

2022-08-02, 1401/05/11

**Ethics committee reference number**

IR.MAZUMS.REC.1401.262

**Health conditions studied****1****Description of health condition studied**

Pain caused by MS

**ICD-10 code**

G35

**ICD-10 code description**

Multiple sclerosis

**Primary outcomes****1****Description**

Intensity of pain caused by MS

**Timepoint**

Weeks 0-4-8-12

**Method of measurement**

Brief pain index (BPI)

**2****Description**

Intensity of pain caused by MS

**Timepoint**

Weeks 0-4-8-12

**Method of measurement**

NPSI (Neuropathic Pain Symptom Inventory )

### 3

#### **Description**

The overall improvement rate of MS patients after taking lacosamide

#### **Timepoint**

Weeks 0-4-8-12

#### **Method of measurement**

Patient Global Impression of Change (PGIC).

### 4

#### **Description**

The safety of lacosamide in improving pain caused by MS.

#### **Timepoint**

Weekly

#### **Method of measurement**

Patient tolerability

## **Secondary outcomes**

### 1

#### **Description**

Determining the improvement in function and quality of life of patients with MS following the use of lacosamide

#### **Timepoint**

Weeks 0-8-12

#### **Method of measurement**

Item Short Form Survey (SF-36)

## **Intervention groups**

### 1

#### **Description**

Intervention group: Half of the patients in the lacosamide group received lacosamide tablets 100 mg twice a day in the first week, and from the second week, the dose was prescribed as 150 mg every 12 hours, and in the third week, 200 mg twice a day if tolerated. In weeks 0, 4, 8 and 12, they are visited by a neurologist.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Half of the patients in the control group receive a placebo in the form of tablets with the same color, size and packaging as the intervention group and without the active pharmaceutical ingredient every 12 hours.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

#### **Name of recruitment center**

Ibn Sina hospital

#### **Full name of responsible person**

Monireh Ghazaeian

#### **Street address**

Ibn Sina hospital, Pasdaran Blvd

#### **City**

Sari

#### **Province**

Mazandaran

#### **Postal code**

4815733971

#### **Phone**

+98 11 3448 4800

#### **Fax**

+98 11 3335 2725

#### **Email**

Ghazaeianm@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

Pedram Ebrahimnejad

##### **Street address**

Vice chancellor for Research, Mazandaran University of medical Sciences, Joybar 3way, Sari,Iran

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

4815733971

##### **Phone**

+98 11 3448 4800

##### **Fax**

+98 11 3335 2725

##### **Email**

pebrahimnejad@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**

Monireh Ghazaeian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical pharmacy

**Street address**

Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 33343011

**Email**

Ghazaeianm@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Monireh Ghazaeian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical pharmacy

**Street address**

Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3334 3011

**Email**

Ghazaeianm@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Monireh Ghazaeian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical pharmacy

**Street address**

Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3334 3011

**Email**

Ghazaeianm@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data related to the initial outcomes of the study will be shared

**When the data will become available and for how long**

The data will be available one year after publication

**To whom data/document is available**

Academic researchers, medical team and scientific institutes

**Under which criteria data/document could be used**

Requests for sharing data should be sent to the person responsible for general inquiries

**From where data/document is obtainable**

Requests for sharing data should be sent to the person responsible for general inquiries.

Ghazaeianm@gmail.com

**What processes are involved for a request to access data/document**

Person in charge of scientific study will reply to the request within 10 days.

**Comments**