

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

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+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

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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

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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

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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