Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Lacosamide efficasy 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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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 efficasy and safety on pain in patients with multiple sclerosis: A randomized double_blind clinical trial

Public title
Lacosamide efficasy 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 elevator 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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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

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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
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 outcoms 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 reseachers, 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