Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of lidocaine spray in reducing ophthalmic neuralgia in patients with multiple sclerosis

Protocol summary

Study aim
Determining the effect of lidocaine spray in reducing ophthalmic neuralgia in patients with multiple sclerosis

Design
Clinical trial, with parallel groups, randomized, double-blind, phase 2-3 on 76 patients, Random allocation software will be used for randomization.

Settings and conduct
Total sample is 76 people in 2 groups and it is from the clients to the clinics covered by the University of Medical Sciences in the city of Sari and randomly per week. The patients are randomly divided into 2 groups of control and placebo, and one group of lidocaine 10% and the other group of normal nasal spray. They use saline and do not need to be assimilated. After each course of treatment, they are evaluated in terms of the amount of pain reduction by visual analog scale. Participants will be instructed to take 2 puffs of the spray (equivalent to 0.2 mg) at the time of pain..Pain will be measured at 15 minutes, 2, 8 and 24 hours after the intervention in both target and placebo groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definite MS confirmed by MRI Confirmation of ophthalmic neuralgia without response to drug treatment Performing a lidocaine sensitivity test and proving the absence of lidocaine sensitivity The patient's willingness to participate in the study and obtain informed consent The patient's MS must be of the relapsing remitting type and must have been approved by a neurologist. Exclusion criteria: Occurrence of drug side effects Worsening of symptoms. Patient dissatisfaction More than three months have passed since the diagnosis of their disease and they have entered the chronic phase

Intervention groups
People are randomly divided into two control and placebo groups, and one group uses 10% lidocaine and the other group uses normal saline nasal spray.

Main outcome variables
The intensity of the conflict؛ The intensity of the patient's pain؛ Pain-free time after each use.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231029059896N1**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date
2023-11-13, 1402/08/22

Registrant information

Name
maryam daneshian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of lidocaine spray in reducing ophthalmic neuralgia in patients with multiple sclerosis

Public title
The effect of lidocaine spray in reducing ophthalmic neuralgia in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definite MS confirmed by MRI Confirmation of ophthalmic neuralgia without response to drug treatment Performing a lidocaine sensitivity test and proving the absence of lidocaine sensitivity The patient's willingness to participate in the study and obtain informed consent The patient's MS must be of the relapsing remitting type and must have been approved by a neurologist.

Exclusion criteria:
Occurrence of drug side effects Worsening of symptoms. Patient dissatisfaction More than three months have passed since the diagnosis of their disease and they have entered the chronic phase

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
All identified patients will be included in the study and there is no need to calculate the sample size. The total sample size in two groups is 76 people, which is due to the fact that people enter the treatment center on weekdays by accident. First, eligible patients are taken from the average admission unit and then they are randomly divided into two groups based on the number of eligible patients. This is because the size of the two groups is almost equal, while the sample size in each group is 34 people, after considering 10% attrition, 38 people in each group and a total of 76 people are selected. For random assignment Random Allocation software was used for two groups and they were selected in blocks of 8 and assigned to two study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
After selecting the samples, none of the samples will be aware of the randomization and the process of allocating groups. Patients enter the study numbers in order. Lidocaine and normal saline spray is in the same packaging and the color of both consumed is the same. The time of spray use is in the pain time and this will be explained to the participants to consume 2 puffs of spray (equivalent to 1.2 mg). The evaluation at all stages mentioned above is the student who is unaware of the drugs. In our study, the patient and the evaluation have been blinded. And the neurologist is aware of the prescription drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of mazandaran of medical sciences

Street address
Mazandaran University of medical sciences, at the begining of Valiasr Highway, Joibar three ways, imam Square,Sari, Mazndaran Province

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Sari

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Mazandaran

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Approval date
2023-09-23, 1402/07/01

Ethics committee reference number
IR.MAZUMS.REC.1402.422

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
The primary outcome of the patient's pain intensity based on Visual Analogue Scale (VAS) criteria

Timepoint
Before using the spray

Method of measurement

These outcomes are measured by a neurologist based on the VAS

Secondary outcomes

1

Description
Measurement of pain-free time after each use of the spray
Timepoint
The pain-free period after using the spray during pain is recorded in 0-6-12-24 hours and more than one week from the patients.
Method of measurement
These outcomes are measured by the evaluator, who is a final year medical student who is not aware of the assignment of the subjects to each of the two allocation groups and the drugs used. Pain-free time after using the spray during pain in hours 0-6-12-24 and more than one week of patients are recorded. The instrument for measuring this variable is based on the patient's statements and its unit is amount of hours.

Intervention groups

1

Description
Intervention group : 10% lidocaine nasal spray, 2 puffs of the spray (equivalent to 0.2 mg) to be used during pain.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sari Buali Sina Hospital
Full name of responsible person
Maryam Daneshian
Street address
Buali Sina Hospital, First of Ghaemshahr road. Sari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Dr Maryam Daneshian
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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