Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the clinical effect and side effects of lacosamide with topiramate in controlling migraine headaches during 3 months

Protocol summary

Study aim

The studies on lacosamide are very limited, and there have been no comparative studies on lacosamide and topiramate in the prevention of migraine attacks. Given the high prevalence of migraines and the lack of effective preventive treatments, it is essential to investigate effective therapies and compare them to achieve the best treatment methods. Therefore, the aim of the present study is to compare the clinical effects and side effects of lacosamide with topiramate in the control of migraine headaches over a period of 3 months.

Design

A clinical trial with a control group, using a parallel three-arm double-blind design, involving 60 patients.

Settings and conduct

The study participants include all patients with diagnosed migraine headaches who are referred to Shahid Beheshti Hospital in Qom and are selected through simple random sampling. After entering the study and obtaining consent, diagnostic and therapeutic measures are performed for all patients upon entry into the study according to the protocol for managing patients, based on the decision of the responsible physician.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Individuals with migraine headaches Exclusion Criteria: Individuals under 18 years of age Pregnant women Individuals with cardiovascular diseases

Intervention groups

The study participants include all patients with diagnosed migraine headaches who are referred to Shahid Beheshti Hospital in Qom.

Main outcome variables

Studies on lacosamide are very limited, and there have been no comparative studies on lacosamide and topiramate in the prevention of migraine attacks. Given the high prevalence of migraines and the lack of effective treatments for preventing migraine attacks, it is essential to investigate effective therapies and compare them to achieve the best treatment methods.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240930063218N1**
Registration date: **2024-12-19, 1403/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-19, 1403/09/29**
Update count: **0**

Registration date

2024-12-19, 1403/09/29

Registrant information

Name

Mohammad javad Khadem

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-31, 1403/08/10

Expected recruitment end date

2025-01-29, 1403/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the clinical effect and side effects of lacosamide with topiramate in controlling migraine headaches during 3 months

Public title
Comparison of the clinical effect and side effects of lacosamide with topiramate in controlling migraine headaches

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with migraine headache

Exclusion criteria:
Under 18 years old Pregnant women Cardiovascular diseases

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: block Randomization Unit: Individual Randomization tool: questionnaire and software

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients are treated with pre-determined drug packages by the study supervisor (supervisor). The drug packages are identical in appearance, and both the patient and the study implementer are unaware of the contents of the packages. Additionally, data collection, patient assessment, and form completion are carried out by the study implementer and their assistant, who are also unaware of the contents of the packages. In the data analysis phase, the analysis is conducted by the study supervisor and the study implementer, who are unaware of the contents of the drug packages, and only the patient groups (Group 1 or Group 2) are identified for data analysis. Therefore, the study is triple-blind, and from the moment the patient enters the study until the completion of the study, data collection, and information analysis, the contents of the two drug groups remain unknown.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qom University of Medical Sciences

Street address
Shahid beheshti

City
Qom

Province
Ghoum

Postal code
3719964797

Approval date
2024-07-22, 1403/05/01

Ethics committee reference number
IR.MUQREC.1403.118

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Intensity and frequency of headaches

Timepoint
3 months

Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study is designed as a triple-blind randomized clinical trial. All patients meeting the inclusion criteria will be considered for participation in the study at the time of enrollment. After obtaining

written informed consent and explaining the study conditions, patients will be asked to rate their pain level based on the VAS scale. They will then be randomly assigned to one of the study groups. The first group will receive topiramate (manufactured by Darou Pakhsh Company, Tehran, Iran), and the second group will receive lacosamide (manufactured by Caspian Darou Company, Rasht, Iran). It is important to note that patients receiving lacosamide will also be monitored with ECG.In the lacosamide group, patients will receive 100 mg of lacosamide twice daily in the first week, 150 mg every 12 hours in the second week, and 200 mg twice daily in the third week, if tolerated. In the topiramate group, patients will receive 25 mg of topiramate once daily in the first week, followed by 25 mg twice daily thereafter.Patients will be grouped based on the Balanced Randomization method into two groups, A and B. Both analgesic medications will be placed in boxes A and B, with only the responsible physician (the principal investigator) aware of the contents of each group. Each patient will then be assigned a number by the principal investigator, which will be recorded in a notebook. For example, patient number 1 will receive medication A, and patient number 2 will receive medication B, or vice versa, with the blinding method explained below.It is worth noting that both groups of patients will continue their routine migraine treatment, and routine treatment will not be discontinued. In the event of a headache, patients will be given analgesics to ensure they receive effective treatment, which will include various NSAIDs.

Category
Treatment - Drugs

2

Description
Intervention group: In the lacosamide group, patients will receive 100 mg of lacosamide twice daily in the first week, 150 mg every 12 hours in the second week, and 200 mg twice daily in the third week, if tolerated. In the topiramate group, patients will receive 25 mg of topiramate once daily in the first week, followed by 25 mg twice daily thereafter

Category
Treatment - Drugs

3

Description
Control group: In the topiramate group, patients will receive 25 mg of topiramate once daily in the first week, followed by 25 mg twice daily thereafter.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qom shahid beheshti hospital
Full name of responsible person
Mohammad javad khadem
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Research DepartmentResident

Position
Resident
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available