

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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Migraine
ICD-10 code	G43
ICD-10 code description	Migraine
Primary outcomes	
<u>1</u>	
Description	Intensity and frequency of headaches
Timepoint	3 months
Method of measurement	Visual analogue scale
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
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

Full name of responsible person

Research Department

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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

Medical doctor

Other areas of specialty/work

Neurology

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Latest degree

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Neurology

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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