

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluating the effect of Lacosamide treatment on the severity of headache attacks and CGRP-LI levels in people with migraine: A triple-blind randomized clinical trial

Protocol summary

Study aim

To evaluate the effects of Lacosamide treatment on the severity of migraine attacks and CGRP-LI levels using a triple-blind randomized clinical trial

Design

Triple-blind randomized clinical trial, where patients, prescribing physicians, and investigators are blinded to group allocation

Settings and conduct

The clinical trial is a triple-blind randomized study conducted at Imam Khomeini Hospital Complex's Neurology Clinic, Tehran University of Medical Sciences, Iran

Participants/Inclusion and exclusion criteria

Patients aged 18-45 diagnosed with migraine based on ICHD-3 criteria, and have not used any preventive medication in the past month

Intervention groups

Intervention Group: Receives Lacosamide (50 mg BID) daily for 3 months Placebo Group: Receives identical-looking placebo for 3 months

Main outcome variables

Measurement of CGRP-LI levels via ELISA test and migraine severity using MIDAS questionnaire before and after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250525065882N1**

Registration date: **2025-06-15, 1404/03/25**

Registration timing: **prospective**

Last update: **2025-06-15, 1404/03/25**

Update count: **0**

Registration date

2025-06-15, 1404/03/25

Registrant information

Name

Iman Kiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2284 8546

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-21, 1404/03/31

Expected recruitment end date

2025-12-04, 1404/09/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Lacosamide treatment on the severity of headache attacks and CGRP-LI levels in people with migraine: A triple-blind randomized clinical trial

Public title

Lacosamide in Migraine

Purpose

Treatment

Inclusion/Exclusion criteria

	Inclusion criteria: The patients' age should be between 18 and 45 years They must have migraine disease according to the ICHD-3 criteria They must not have used migraine preventive medication in the past month The patient must have the ability to respond to questions
	Exclusion criteria: Lack of patient consent to participate in the study Lacosamide medication interfere with other drugs received by the patient
	Age From 18 years old to 45 years old
	Gender Both
	Phase 3
	Groups that have been masked • Participant • Care provider • Investigator
	Sample size Target sample size: 44
	Randomization (investigator's opinion) Randomized
	Randomization description Using a random number table, patients will be randomly assigned to intervention and control groups. The table consists of a large set of numbers generated without a specific pattern and organized into a structured format. To apply this method, the researcher first designates sequential numbers for different groups, such as 0-22 for the intervention group and 23-44 for the placebo group. The researcher then selects a starting number, proceeds in a predetermined direction, records the numbers, and allocates them accordingly to the designated groups.
	Blinding (investigator's opinion) Triple blinded
	Blinding description In this study, both the patients and the prescribing physician will remain unaware of the nature of the drug and placebo, as well as the randomization process. Additionally, the researcher and statistical consultant will serve as a third blinded arm and will be subject to blinding procedures. An external observer will be aware of the drug and placebo but will have no role in their allocation. The placebo will be identical to the drug in terms of size, color, volume, and packaging. The required placebo will be sourced from the pharmaceutical company Kondor Pharma.
	Placebo Used
	Assignment Parallel
	Other design features
	Secondary Ids empty

Ethics committees
1
Ethics committee
Name of ethics committee Research Ethics Committees of Neuroscience Institute
Street address Keshavarz Blvd., Tehran, Iran
City Tehran
Province Tehran
Postal code 1419733131
Approval date 2025-02-04, 1403/11/16
Ethics committee reference number IR.TUMS.NI.REC.1403.059

Health conditions studied
1
Description of health condition studied migraine
ICD-10 code G43
ICD-10 code description Migraine
Primary outcomes
1
Description Migraine duration
Timepoint Month
Method of measurement Ask the patient

2
Description Migraine intensity
Timepoint Baseline (before treatment) and after 3 months
Method of measurement MIDAS questionnaire, completed by patients

3
Description The concentration of Calcitonin Gene-Related Peptide (CGRP-LI) in the blood, linked to migraine
Timepoint Baseline (before treatment) and after 3 months
Method of measurement ELISA test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive Lacosamide medication daily at a dose of 50 mg provided by Actover Company for a duration of three months.

Category

Treatment - Drugs

2

Description

Intervention group: The placebo group will receive the placebo for three months at the same dosage as the medication prescribed to the other group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Abbas Tafakhori

Street address

End of Keshavarz Blvd., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Iman Kiani

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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