Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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
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Iran (Islamic Republic of)
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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
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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
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Person responsible for updating data

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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