

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Email address

i-kiani@student.tums.ac.ir

##### 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

##### City

Tehran

##### Province

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1419733141

##### Phone

+98 911 156 3230

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abbas.tafakhori@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Ramin Kordi

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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

Neurology

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## Person responsible for scientific inquiries

#### Contact

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Abbas Tafakhori

##### Position

Professor

##### Latest degree

Specialist  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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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