

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effects of lacosamide and topiramate versus topiramate and placebo combination therapy on headache in patients with chronic migraine: A randomized double-blind clinical trial

Protocol summary

Study aim

Evaluating the effectiveness of topiramate and lacosamide combination therapy in improving migraine headaches

Design

A clinical trial with control group and parallel group design, phase 3 on 74 patients. Randomization will be done using random number table (permuted block method using blocks of size 4).

Settings and conduct

Place of study: Ibn Sina Clinic, Sari, Mazandaran province; Study population: patients who have been diagnosed with chronic migraine based on ICHD-3 beta criteria and who includes inclusion criteria and do not have the exclusion criteria; Blinding type: double blind

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adults over 18 years old with migraine (with aura or without aura) with a complaint of moderate to high intensity migraine headache ($VAS \geq 4$); Non-inclusion criteria: Severe depression or suicidal thoughts; Thyroid disorders; pregnancy or lactation; History of ischemic cerebral disease or ischemic heart disease; Renal dysfunction (GFR less than 30 ml/min); medication overuse headache

Intervention groups

Intervention group: In the first week, all patients will receive lacosamide 100 mg twice a day, and from the second week, they will also receive 150 mg every 12 hours, and in the third week, 200 mg twice a day, if they tolerate, and they will also receive topiramate 25 mg once a day in the first week and after that 25 mg twice a day. Control group: all patients will receive placebo with the same shape and color as lacosamide twice a day, and they will also receive topiramate 25 mg once a day in the first week and after that 25 mg twice a day.

Main outcome variables

The number of days a person experiences headache; the

number of headache attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190804044429N9**

Registration date: **2022-09-20, 1401/06/29**

Registration timing: **prospective**

Last update: **2022-09-20, 1401/06/29**

Update count: **0**

Registration date

2022-09-20, 1401/06/29

Registrant information

Name

Monireh Ghazaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 6864

Email address

ghazaeianm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of lacosamide and topiramate versus topiramate and placebo combination therapy on headache in patients with chronic migraine: A randomized double-blind clinical trial

Public title

The effects of lacosamide and topiramate combination therapy on chronic migraine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adults over 18 years old migraine (with or without aura) moderate to high intensity migraine headache (VAS $\geq$ 4)

Exclusion criteria:

Severe depression or suicidal thoughts Thyroid disorders Pregnancy Lactation History of ischemic cerebral disease or ischemic heart disease Renal dysfunction (GFR less than 30 ml/min) medication overuse headache History of drug abuse and alcohol History of hepatic failure A history of cardiac arrhythmia or using drugs that affect heart rhythm

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block method will be used to allocate the samples to two groups. Blocks will be considered as blocks of size 4 and in each block of 4 people, two people in the intervention group and two people in the control group will be selected. The selection of the order type for each person in each group will be done through second version of random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind. Medicines and placebo in the same color and size forms will be packed in medicine envelopes of the same shape and color and will be provided to the patients. Outcome evaluator and participant are blinded (double blind) and aware from grouping (intervention or placebo).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mazandaran University of Medical Sciences

Street address

Ibn Sina Hospital, Pasharan Blvd

City

Sari

Province

Mazandaran

Postal code

4816864193

Approval date

2022-08-08, 1401/05/17

Ethics committee reference number

IR.MAZUMS.REC.1401.253

Health conditions studied**1****Description of health condition studied**

Migraine Headache

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

The number of days that the individual has experienced headache

Timepoint

At the beginning of the study, in the 8th week (56 days after baseline) and in the 11th week (84 days after baseline)

Method of measurement

History taking

2**Description**

The number of headache attacks

Timepoint

weekly, up to 12 weeks

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes

1

Description

Disability improvement

Timepoint

Baseline and third month

Method of measurement

Migraine Disability Assessment

Intervention groups

1

Description

Intervention group: In the first week, all patients will receive lacosamide 100 mg twice a day, and from the second week, they will also receive 150 mg every 12 hours, and in the third week, 200 mg twice a day, if they tolerate, and they will also receive topiramate 25 mg once a day in the first week and after that 25 mg twice a day.

Category

Treatment - Drugs

2

Description

Control group: all patients will receive placebo with the same shape and color as lacosamide twice a day, and they will also receive topiramate 25 mg once a day in the first week and after that 25 mg twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Ibn Sina hospital

Full name of responsible person

Monireh Ghazaeian

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Ibn Sina hospital, Pasdaran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar three-way , Sari

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majsaeedi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Monireh Ghazaeian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data related to the initial outcomes of the study will be shared

When the data will become available and for how long

The data will be available one year after publication

To whom data/document is available

Academic researchers, medical team and scientific institutes

Under which criteria data/document could be used

Requests for sharing data should be sent to the person responsible for general inquiries

From where data/document is obtainable

Requests for sharing data should be sent to the person responsible for general inquiries.
ghazaeianm@gmail.com

What processes are involved for a request to access data/document

Person in charge of scientific study will reply to the request within 10 days.

Comments