Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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≥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
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Monireh Ghazaeian
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
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 toptramate 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≥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 elevator 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, Pasdaran 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
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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?
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
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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