

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

COMPARISON OF EFFICACY OF ORAL LACOSAMIDE VERSUS ORAL TOPIRAMATE IN YOUNG ADULTS WITH CHRONIC MIGRAINE

Protocol summary

Study aim

The objective of this study is to compare the efficacy of the new anti-epileptic drug lacosamide when compared with conventional treatment with topiramate for the treatment of young adults with chronic migraine

Design

Quasi experimental interventional study

Settings and conduct

Double blinded with the doctor and patient unaware of the study protocol with the doctor advising the interventional drug to the patient in sealed envelopes from the department

Participants/Inclusion and exclusion criteria

All male and female patients aged 18-30 diagnosed with migraine according to the ICHD 3 criteria and having chronic migraine will be included Patients with diabetes and hypertension or critical respiratory, renal or cardiac disease, patients with allergy to lacosamide or topiramate and patients unwilling to be included in the study will be excluded

Intervention groups

Two Groups Group L receiving Oral Lacosamide 150 mg twice a day Group T receiving Oral Topiramate 50 mg twice a day

Main outcome variables

Frequency of acute attacks in the following three months of therapy and improvement seen by standard Chronic headache quality of life questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230809059091N1**

Registration date: **2023-08-09, 1402/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-09, 1402/05/18**

Update count: **0**

Registration date

2023-08-09, 1402/05/18

Registrant information

Name

Nabeel Butt

Name of organization / entity

Combined Military Hospital Rahim Yar Khan

Country

Pakistan

Phone

+92 313 5969696

Email address

nabeel4allz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-09, 1402/05/18

Expected recruitment end date

2023-11-09, 1402/08/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

COMPARISON OF EFFICACY OF ORAL LACOSAMIDE VERSUS ORAL TOPIRAMATE IN YOUNG ADULTS WITH CHRONIC MIGRAINE

Public title

ORAL LACOSAMIDE AND ORAL TOPIRAMATE IN PREVENTING MIGRAINE ATTACKS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ALL PATIENTS AGED 18-30 YEARS DIAGNOSED WITH MIGRAINE ACCORDING TO THE ICHD 3 CRITERIA PATIENTS WITH CHRONIC MIGRAINE AS HEADACHE OCCURRING ON 15 OR MORE DAYS PER MONTH FOR MORE THAN THREE MONTHS, WHERE AT LEAST 8 OF THOSE HEADACHE DAYS HAVE MIGRAINE FEATURES

Exclusion criteria:

PATIENTS WITH KNOWN HYPERTENSION, DIABETES OR ADVANCED CARDIAC OR RESPIRATORY DISEASE PATIENTS WITH ALLERGY TO EITHER LACOSAMIDE OR TOPIRAMATE PATIENTS WITH AN ACUTE EPISODE OF MIGRAINE IN THE LAST ONE WEEK

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **250**

Randomization (investigator's opinion)

Randomized

Randomization description

METHOD OF SAMPLING BETWEEN BOTH GROUPS WAS NON-PROBABILITY CONSECUTIVE SAMPLING BY LOTTERY METHOD

Blinding (investigator's opinion)

Double blinded

Blinding description

SEALED ENVELOPES WITH MEDICATIONS MARKED A AND B GIVEN TO THE PATIENTS WITH NEITHER THE DOCTOR OR THE PATIENT KNOWING WHICH ENVELOPED CONTAINED WHICH DRUG

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical review board CMH RYK

Street address

Chowk Bahadarpur

City

Rahim Yar Khan

Postal code

64200

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

00100

Health conditions studied

1

Description of health condition studied

Chronic migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Frequency of migraine attacks and improvement in quality of life

Timepoint

Three months post-intervention

Method of measurement

Standardized Chronic headache quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group L (Oral Lacosamide)

Category

Treatment - Drugs

2

Description

Intervention group: Group T (Oral Topiramate)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined Military Hospital Rahim Yar Khan

Full name of responsible person

Dr. Nabeel Tahir Butt

Street address

Chowk Bahadarpur

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Combined Military Hospital Rahim Yar Khan
Full name of responsible person
Dr. Nabeel Tahir Butt
Street address
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City
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Grant name
None
Grant code / Reference number
None
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
None
Proportion provided by this source
1
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Combined Military Hospital Rahim Yar Khan
Full name of responsible person
Dr. Nabeel Tahir Butt
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology

Person responsible for scientific inquiries

Contact

Name of organization / entity
CMH Rahim Yar Khan
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Will only be shared after study peer reviewed and published after approval by the journal

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Available in the text of the article

When the data will become available and for how long

Will be available indefinitely after approval by the journal

To whom data/document is available

Everyone having access to article text

Under which criteria data/document could be used

None

From where data/document is obtainable

Via email provided

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

Email to the institute and concerned professional

Comments