Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 recieving 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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nabeel4allz@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Combined Military Hospital Rahim Yar Khan
Full name of responsible person
Dr. Nabeel Tahir Butt
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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
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Person responsible for updating data

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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