Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of lacosamide in patients with diabetic neuropathy

Protocol summary

Study aim
To compare the effectiveness of lacosamide versus placebo in reducing neuropathic pain in patients with diabetic peripheral neuropathy.

Design
Randomized, double-blind, placebo-controlled, parallel-group clinical trial

Settings and conduct
Conducted at the Department of Medicine, Nishtar Hospital Multan, after ethical approval. Patients enrolled consecutively, treated and followed for 12 weeks with 4-weekly assessments.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 20–60 years, either gender, Diabetes mellitus >5 years, VAS pain score >4, Informed consent given, Exclusion Criteria: Cardiovascular disease, Renal impairment or liver enzymes >2× normal, Pregnant or breastfeeding, Using other neuropathic pain medications (e.g., TCAs, lidocaine patch, mexiletine, tramadol, opioids, AEDs, NSAIDs)

Intervention groups
Intervention group: Participants will receive Lacosamide (C13H18N2O3) tablets manufactured by Zakfas Pharmaceuticals Private Limited, orally. Dose will begin at 100 mg once daily, increased weekly by 100 mg to a maximum of 400 mg/day (200 mg twice daily) by week 4. This dose will be maintained for 12 weeks. Tablets will be provided in sealed identical packaging to ensure blinding. Follow-up will occur every 4 weeks. Control group: Participants will receive placebo tablets identical in appearance and schedule to the intervention group. Placebo will be manufactured by Zakfas Pharmaceuticals Privat Limited.Placebo contains inactive ingredients only and will be administered orally for 12 weeks using the same titration schedule to maintain blinding. Follow-ups will occur every 4 weeks.

Main outcome variables
Main Outcome Variable: Mean pain score after 12 weeks, measured using Visual Analogue Scale (VAS).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250211064704N1**
Registration date: **2025-05-21, 1404/02/31**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-21, 1404/02/31**
Update count: **0**

Registration date
2025-05-21, 1404/02/31

Registrant information

Name
Dr Awais Akram

Name of organization / entity
Nishtar Medical University, Multan Pakistan

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-01, 1403/12/11

Expected recruitment end date
2026-01-01, 1404/10/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Efficacy of lacosamide in patients with diabetic neuropathy

Public title
Efficacy of lacosamide in patients with diabetic neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
known case of Diabetes with equivalent or more than 5 years of diabetes Patients of either gender Age 20-60 years
Exclusion criteria:
Patient taking other medicine for pain (TCA, lidocaine patch, mexiletine hydrochloride, tramadol, opioids, AEDs and NSAIDS) Patients with cardio-vascular disease pregnant / breastfeeding women Patient with renal impairment Patients with liver functioning enzymes greater than twice of normal
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomized individually into two groups (Group A: Lacosamide, Group B: Placebo) using a simple randomization method. A computer-generated random number sequence will be prepared in advance using randomization software (e.g., www.randomizer.org). The sequence will be generated by a person not involved in participant enrollment. Allocation will be concealed using sequentially numbered, sealed, opaque envelopes (SNOSE) containing the group assignment. Each envelope will be opened only after the patient has been enrolled and consented. The envelopes will be identical and opaque to prevent selection bias, ensuring allocation concealment. This process guarantees that the assignment remains unpredictable and unbiased.
Blinding (investigator's opinion)
Double blinded
Blinding description
This will be a double-blinded study in which both the participants and the investigator assessing outcomes will be blinded to the treatment allocation. Lacosamide and placebo tablets will be identical in appearance, packaging, color, and size, and will be labeled with coded identifiers (e.g., A or B) by a third party not involved in participant recruitment or outcome assessment. The medication codes will be kept confidential and secured until the completion of data analysis. The investigator responsible for enrolling participants and recording outcomes will not have access to the allocation code. The blinding will be maintained throughout the study to minimize performance and assessment bias. Unblinding will only occur in case of medical emergency or serious adverse event where knowledge of the treatment is necessary for clinical decision-making.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Review Board/committee Nishtar Medical University, Multan
Street address
No 1 , Nishtar street, Nishtar Hospital Road, Gilani Colony Nishtar Multan
City
Multan
Postal code
66000
Approval date
2025-03-10, 1403/12/20
Ethics committee reference number
3607/NMU

Health conditions studied

1

Description of health condition studied
Diabetic Neuropathy
ICD-10 code
E11.40
ICD-10 code description
Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Mean post-treatment pain score in patients with diabetic neuropathy after receiving either Lacosamide or placebo for 12 weeks.
Timepoint
12 weeks (at the end of the treatment period).
Method of measurement

Pain intensity will be measured using the Visual Analogue Scale (VAS), where 0 indicates no pain and 10 indicates worst possible pain. The outcome will be assessed by a blinded assessor who is unaware of the group allocation.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants will receive Lacosamide tablets (C13H18N2O3), manufactured by Zakfas Pharmaceuticals (Pvt.) Ltd, Pakistan. Treatment will begin at 100 mg orally once daily, increasing weekly in 100 mg increments to a maximum of 400 mg/day (200 mg twice daily): Week 1: 100 mg once daily; Week 2: 100 mg twice daily; Week 3: 200 mg morning, 100 mg evening (300 mg/day); Week 4–12: 200 mg twice daily. Treatment will continue for 12 weeks. Medication will be administered orally. Tablets will be identical in appearance to placebo. Participants will be assessed every 4 weeks for adherence, side effects, and outcomes.

Category
Treatment - Drugs

2

Description
Control group: Participants will receive placebo tablets, identical in size, shape, and color to the Lacosamide tablets, manufactured by Zakfas Pharmaceuticals (Pvt.) Ltd, Pakistan. The placebo will be administered orally for 12 weeks, following the same titration schedule as the intervention group: Week 1: 1 tablet once daily; Week 2: 1 tablet twice daily; Week 3: 2 tablets in the morning, 1 in the evening (to mimic 300 mg/day dosing); Week 4–12: 2 tablets twice daily. The placebo dosing schedule will simulate the active drug regimen to maintain blinding. Participants will be monitored every 4 weeks for adherence, side effects, and outcome assessments.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Nishtar Medical University and Hospital Multan

Full name of responsible person
Dr Awais Akram

Street address
No 1 , Nishtar street, Nishtar Hospital Road, Gilani Colony Nishtar Multan

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Web page address
https://nmu.edu.pk/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nishtar Medical University and Hospital Multan

Full name of responsible person
Dr Shahzad Alam Khan

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Ward 11 , No 1 , Nishtar street, Nishtar Hospital Road, Gilani Colony Nishtar Multan

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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
Nishtar Medical University and Hospital Multan

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
Nishtar Medical University and Hospital Multan

Full name of responsible person
Dr Awais Akram

Position
Post Graduate Trainee

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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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
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study Protocol (methods, randomization details). Statistical Analysis Plan (how data will be analyzed). Summary Results (aggregate data, no personal identifiers). De-identified Participant Data (only if ethically approved).
When the data will become available and for how long
After publication of primary results, typically 6–12 months post-study completion. Data will be available for at least 5 years after publication.
To whom data/document is available
Researchers; Healthcare providers .
Under which criteria data/document could be used
Ethical & Confidentiality Considerations. De-identification: All participant data will be anonymized to prevent identification. Ethical Approval: Data sharing will comply with institutional IRB guidelines. Patient Consent: Informed consent forms will include a clause about potential data sharing.
From where data/document is obtainable
Institutional Repository: Nishtar Medical University database (if available). Public Repositories: WHO ICTRP, ClinicalTrials.gov, Dryad, or Figshare. Journal Supplementary Files: If required by the journal where the study is published.
What processes are involved for a request to access data/document
Researchers must submit a formal request via email to the principal investigator. Requests should include: Purpose of data use, Ethical approval (if applicable), Data security measures. Access will be granted only for non-commercial, research purposes.
Comments