

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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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+92 335 6025056

Email address

awais.szmc@gmail.com

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

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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

Street address

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