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Comparing intravenous lacosamide with intravenous phenytoin for severe flare-ups of trigeminal neuralgia

Submission date	Recruitment status	[ ] Prospectively registered
22/07/2026	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/07/2026	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/07/2026	Nervous System Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Protocol number
112/25

Study information

Scientific Title
A randomized open-label pilot trial comparing intravenous lacosamide with intravenous phenytoin for pain reduction and adverse events in adults with acute exacerbations of trigeminal neuralgia

Study objectives
To compare the effectiveness and safety of intravenous lacosamide versus intravenous phenytoin in adults with acute exacerbations of trigeminal neuralgia. The primary objective was to compare the proportion of participants achieving at least a 50% reduction in pain intensity at 2 hours after infusion. Secondary objectives were to evaluate pain improvement over 24 hours, the need for additional medication, and treatment-related adverse events.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2025, Research Ethics Committee of Manuel Velasco Suárez National Institute of Neurology and Neurosurgery, (Comité de Ética en Investigación, Instituto Nacional de Neurología y Neurocirugía Manuel Velasco Suárez) (Avenida Insurgentes Sur 3877, Colonia La Fama, Alcaldía Tlalpan, Mexico City, 14269, Mexico; +52 55 5606 3822; comite.etica@innn.edu.mx), ref: CEI/218/2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Acute exacerbations of trigeminal neuralgia

Interventions
Participants were randomized in a 1:1 ratio to receive a single intravenous dose of lacosamide or phenytoin. The allocation sequence was implemented using sequentially numbered, sealed envelopes prepared in advance by an independent investigator. The study was open label. Participants allocated to the lacosamide group received lacosamide 200 mg intravenously, infused over a minimum of 15 minutes. Participants allocated to the phenytoin group received

phenytoin 15 mg/kg intravenously at a maximum infusion rate of 50 mg/min.
Before treatment, participants underwent clinical assessment, pain evaluation using a 0–10 numerical rating scale, vital-sign measurement, and electrocardiography. Participants were monitored during and after the infusion. Pain intensity, additional medication requirements, and adverse events were evaluated at 2, 6, 12, and 24 hours after treatment. The 6-, 12-, and 24-hour assessments were conducted using structured telephone follow-up after discharge when applicable. Total participant follow-up was 24 hours.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lacosamide, phenytoin

Primary outcome(s)
1. Clinically significant pain reduction, defined as the proportion of participants achieving at least a 50% reduction in pain intensity from baseline, measured using a 0–10 numerical rating scale, at 2 hours after completion of the assigned intravenous infusion

Key secondary outcome(s)

Completion date
28/05/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Diagnosis of classical, secondary, or idiopathic trigeminal neuralgia according to the International Classification of Headache Disorders, third edition (ICHD-3)
3. Acute exacerbation, defined as a sudden increase in pain frequency or intensity that is not controlled with the participant’s usual oral treatment
4. Requirement for intravenous treatment in a hospital or emergency department setting
5. Written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
57

Key exclusion criteria
1. Known hypersensitivity to lacosamide or phenytoin
2. Use of lacosamide during the previous two weeks
3. Clinically relevant cardiac arrhythmia, particularly uncontrolled second- or third-degree atrioventricular block
4. Severe hepatic impairment
5. Severe renal impairment
6. Pregnancy or breastfeeding
7. Active epileptic seizures

Date of first enrolment
01/12/2025

Date of final enrolment
27/05/2026

Locations

Countries of recruitment
Mexico

Sponsor information

Organisation
Instituto Nacional de Neurología y Neurocirugía

ROR
https://ror.org/05k637k59

Funder(s)

Funder type

Funder Name
National Institute of Neurological Disorders and Stroke

Alternative Name(s)
National Institute of Neurological Disorders & Stroke, NIH/National Institute of Neurological Disorders and Stroke, NIH National Institute of Neurological Disorders and Stroke, The National

Institute of Neurological Disorders and Stroke, National Institute of Neurological Disorders and Blindness, National Institute of Neurological and Communicative Disorders and Stroke, Instituto Nacional de Trastornos Neurológicos y Accidentes Cerebrovasculares, NINDS, NINDB, NINCDS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available