# SPENDD: Quantitative Sensory Testing and Analgesic Response for Painful Peripheral Neuropathy.

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years to 80 years old

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

5\. INCLUSION AND EXCLUSION CRITERIA

**Inclusion Criteria:**

Patients eligible for inclusion in this study must fulfill all of the following criteria: 1. Between 18 and 80 years old (inclusive). 2. Have a diagnosis of peripheral neuropathic pain in both feet from generalized distal sensory polyneuropathy based on the following criteria 1. A history of a relevant lesion of the peripheral nervous system, disease, toxic exposure, or no known cause (i.e., idiopathic). 2. Pain distribution in a neuroanatomically plausible distribution consistent with a symmetrical generalized polyneuropathy (i.e., with a "glove and stocking" distal to proximal gradient). 3. DN4 score≥ 4 3. Have experienced the neuropathic pain in the feet for at least 6 months. 4. Have at least one of the following sensory signs upon clinical examination: abnormal pinprick perception, allodynia, hyperalgesia, abnormal light touch perception, abnormal vibratory perception, or abnormal proprioception. 5. Have average daily baseline worst pain intensity in their feet of 4 or greater and less than 10, on a 0-10 numeric rating scale of pain intensity (0 = "no pain," 10= "most intense pain imaginable") as measured on the daily diary during screening from at least 5 measurements. 6. Able to understand and read English. This requirement is to ensure that participants can provide informed consent and complete PROs. 7. Have been on stable dosages of all pain medications or using all non-pharmacologic treatments for neuropathy pain at consistent frequency for at least 1 month and willing and able to stay on those dosages (or use those frequencies) (except acetaminophen rescue) throughout the duration of the study. 8. If taking cannabinoid products for any reason, must be at stable dosages for at least 1 month prior to the screening visit and willing to stay on that dosage for the duration of the study. 9. Willing and able to complete electronic patient-reported outcomes at home using a REDCap link.

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**Exclusion Criteria:**

* Exclusion criteria 10, 13, 14, 20 pertain only to trial protocols that include duloxetine. * Exclusion criterion 11, 19 pertain only to trial protocols that include pregabalin. 1. Taking any opioid medication with a daily mean morphine equivalent (MME) of \> 30. 2. Have a different diagnosis of pain in the feet including but not limited to musculoskeletal pain (e.g., foot arthritis, plantar fasciitis) or lumbar sacral radiculopathy that they rate to be worse than their neuropathic pain in their feet, or that in the opinion of the investigator, precludes the participant from rating their neuropathy pain in their feet. 3. Have a central cause of neuropathic pain (e.g., demyelinating disease, spinal cord injury, Parkinson's disease). 4. Have a history of an inciting traumatic or surgical cause that corresponds with the development of features consistent with a peripheral neuropathy. 5. Bilateral polyradiculopathy, with a distal distribution (i.e., symptoms extending into the feet). 6. History of acute polyneuropathy (e.g., Guillain-Barre Syndrome, acute motor sensory axonal neuropathy \[AMSAN\]) within 6 months prior to Visit 1. 7. Have autoimmune-mediated neuropathy (e.g., RA, lupus Sjogren syndrome, Lyme disease, chronic inflammatory demyelinating polyneuropathy (CIDP)) unless the associated inflammation is controlled and, in the opinion of the investigator, is expected to remain stable throughout the course of the study. 8. Charcot-Marie-Tooth disease in which nociceptive pain from joint deformity confounds assessment of neuropathic pain. 9. Have taken the treatment that caused the participant's neuropathy (e.g., neurotoxic chemotherapy, certain HIV therapies) less than 6 months prior to Visit 1. 10. Have taken duloxetine (at least 60mg/day) in the past 6 months or have taken duloxetine at any dosage within a week prior to the screening visit.** 11. Have taken pregabalin (at least 300mg/day) OR gabapentin (at least 1200mg/day) in the past 6 months or have taken pregabalin or gabapentin at any dosage within a week prior to the screening visit.## 12. Have ever previously taken BOTH pregabalin (or gabapentin) AND duloxetine at sufficient dosages and for a sufficient length of time that, in the opinion of the investigator, the participant should have experienced pain relief if they were going to respond, but they did not receive benefit from EITHER drug. 13. Taking venlafaxine, buproprion, tramadol, or St. John's Wort. Concomitant use of one medication that inhibits the reuptake of serotonin is allowed at certain dosages. (See Appendix A for maximum allowed dosages for common selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TCAs); maximum dosages for other applicable drugs will be decided by the research team leadership composed of a) clinical pharmacist with extensive experience in chronic pain management, b) a physician board-certified in pain medicine and psychiatry, and c) a board-certified neurologist.** 14. Taking a monoamine oxidase inhibitor.** 15. Taking CYP1A2 inhibitors or thioridazine. 16. Have a spinal cord stimulator. 17. Have an active, uncontrolled/unstable medical condition (e.g., neurological, gastrointestinal, renal, hepatic, cardiovascular, pulmonary, metabolic, endocrine, hematological, genitourinary, cancer, or other major disorder), psychotic disorder or any other uncontrolled psychiatric illness that in the opinion of the investigator makes it unsafe to participate or inclusion of the participant will have a negative effect on the study. 18. Had a clinically significant illness or operative procedure within four weeks of screening. 19. Known hypersensitivity to pregabalin. ## 20. Known hypersensitivity to duloxetine.** 21. Known history of chronic kidney disease that in the opinion of the investigator would make it unsafe to participate. 22. Known history of chronic liver disease that in the opinion of the investigator would make it unsafe to participate. 23. Excessive consumption of alcohol (i.e., more than 5 drinks / day for males and more than 4 drinks / day for females). 24. A history of illicit drug use in the past year or planning to take any illicit drugs during the course of the study (other than cannabinoid products). 25. Patients who are at significant risk of suicide, or are a danger to self or others, in the opinion of the investigator, based upon clinical interview and the Columbia-Suicide Severity Rating Scale (C-SSRS) at screening and baseline. Affirmative answer to suicidal ideation questions 4 or 5, within the last 6 months and / or suicidal behavior (actual attempt, interrupted attempt, aborted attempt, and/or preparatory acts/behavior) within the last 2 years are exclusionary. 26. Evidence of cognitive impairment including dementia or a psychiatric condition (e.g., schizophrenia, bipolar disorder) that may interfere with the subject's ability to complete assessments. 27. Amputation of lower limbs (foot, ankle, leg, or thigh). Isolated toe amputations are permitted. 28. Pregnant or planning to become pregnant during the study period or breastfeeding (screened via self-report). 29. Enrolled in another investigational medication trial or a trial of any intervention for pain in your feet. 30. Unable or unwilling to provide informed consent. 31. Any additional reason that, in the opinion of the site investigator, would make it unsafe to participate or inclusion of the participant would hurt the study.

## Conditions & Interventions

**Interventions:**

DRUG: Pregabalin, DRUG: Duloxetine, OTHER: Placebo

**Conditions:**

Painful Peripheral Neuropathy, Diabetic Peripheral Neuropathic Pain (DPN), Chemotherapy Induced Peripheral Neuropathy (CIPN), Idiopathic Peripheral Neuropathy

**Keywords:**

Peripheral Neuropathy, Pregabalin, Duloxetine, QST

## More Information

**Contact(s):** Rachel De Guzman - rachel_deguzman@urmc.rochester.edu

**Principal Investigator:**

**IRB Number:**
**System ID:** NCT06614322

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