

FAST FACTS

URCC 19085 - WIRELESS TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) FOR CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY: A PHASE II CLINICAL TRIAL

Inclusion Criteria

Participants must:

1. Have completed treatment with a platinum agent, taxane, vinca alkaloid, or bortezomib at least 3 months prior to registration. See Appendix 1 for a list of drugs included in these drug classes.
2. Have a clinical diagnosis of CIPN from their physician or physician designee based on the following criteria: bilateral (i.e., present on both sides of the body), abnormal sensory symptoms in their feet or legs (e.g., hot/burning pain, sharp/shooting pain, numbness, tingling, cramping).
3. Report at least 1 non-painful symptom associated with CIPN in their lower limbs (e.g., tingling, burning that isn't reported as painful, numbness)
4. Report at least 2 of the following symptoms in their lower limbs (at their worst) as at least 4 out of 10 on a 0 – 10 NRS: hot/burning pain, sharp/shooting pain, numbness, tingling, cramping at Visit 1 (i.e., Week - 1). Use the CIPN Symptom Inventory – Week Recall form (questions 1-5 ONLY) to assess these symptoms at screening.
5. Be willing and able not to start any new analgesic medications or change the dosages of any current analgesic medications (except acetaminophen (Tylenol) or NSAIDs (i.e., ibuprofen (Advil, Motrin), Naproxen (Aleve)) for the duration of the study.
6. Be able to read English (i.e., is not illiterate, can speak English, and is not blind).
7. Be at least 18 years of age.
8. Have access to a smart phone or device with an Apple or Android operating system that can be used to access the TENS device's App and ability to connect to the internet on a daily basis during the trial.

Exclusion Criteria

Participants must not:

1. Have pre-existing neuropathy of any cause documented in their medical record prior to the start of chemotherapy or respond “yes” to the question “Did you have frequent numbness, tingling, sharp/shooting pain, hot/burning pain, or cramping in your feet before you started your chemotherapy?”
2. Have unilateral CIPN symptoms (i.e., symptoms occur on predominantly only one side of the body).
3. Be currently using a TENS device for any other reason.
4. Be currently taking, or have taken in the past 3 months, medications known to cause neuropathy in a significant portion of patients (list of excluded drugs provided in Appendix 2).
5. Have an acute and symptomatic lower extremity DVT (treated DVT with resolution of symptoms is acceptable for enrollment).
6. Lower extremity edema that is 2+ or greater (i.e., slight indentation that takes less than 15 seconds to rebound)..
7. Have started a new prescription pain medication or altered dosages of a prescription pain medication within the last 2 weeks.
8. Have lower extremity wounds or ulcers.
9. Have a cardiac pace maker or defibrillator.
10. Have epilepsy.
11. Have a leg that is too small or too large for the TENS device to fit securely.
12. Have missing lower limbs or amputations.
13. Have impaired decision making capacity (i.e., requires a legally authorized representative or health care proxy).
14. Be pregnant or planning to get pregnant before expected completion of the study.

SCHEMA

