Cancer Research Consortium of West Michigan
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FAST FACTS

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

Inclusion Criteria

Participants must:

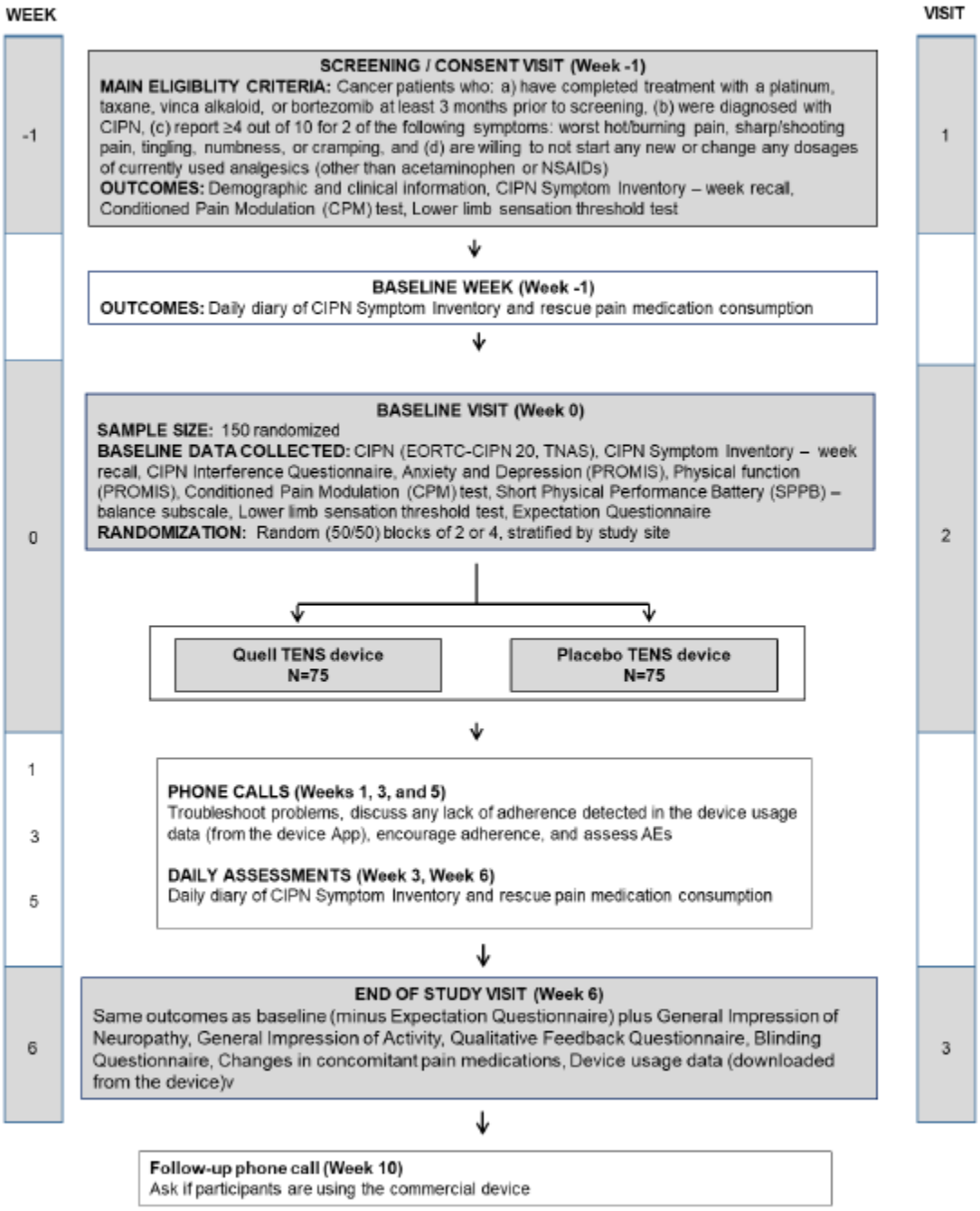
1. Have completed treatment with a platinum agent, taxane, vinca alkaloid, or bortezomib at least 3 months prior to registration. See Appendix 1 for a list of drugs included in these drug classes.
2. Have a clinical diagnosis of CIPN from their physician or physician designee based on the following criteria: 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.
15. Participate in another clinical trial for CIPN

SCHEMA


WEEK
VISIT
-1
1
SCREENING / CONSENT VISIT (Week -1)
MAIN ELIGIBLITY CRITERIA: Cancer patients who: a) have completed treatment with a platinum, taxane, vinca alkaloid, or bortezomib at least 3 months prior to screening, (b) were diagnosed with CIPN, (c) report ≥4 out of 10 for 2 of the following symptoms: worst hot/burning pain, sharp/shooting pain, tingling, numbness, or cramping, and (d) are willing to not start any new or change any dosages of currently used analgesics (other than acetaminophen or NSAIDs)
OUTCOMES: Demographic and clinical information, CIPN Symptom Inventory – week recall, Conditioned Pain Modulation (CPM) test, Lower limb sensation threshold test
BASELINE WEEK (Week -1)
OUTCOMES: Daily diary of CIPN Symptom Inventory and rescue pain medication consumption
0
2
BASELINE VISIT (Week 0)
SAMPLE SIZE: 150 randomized
BASELINE DATA COLLECTED: CIPN (EORTC-CIPN 20, TNAS), CIPN Symptom Inventory – week recall, CIPN Interference Questionnaire, Anxiety and Depression (PROMIS), Physical function (PROMIS), Conditioned Pain Modulation (CPM) test, Short Physical Performance Battery (SPPB) – balance subscale, Lower limb sensation threshold test, Expectation Questionnaire
RANDOMIZATION: Random (50/50) blocks of 2 or 4, stratified by study site
Quell TENS device N=75
Placebo TENS device N=75
1
3
5
PHONE CALLS (Weeks 1, 3, and 5)
Troubleshoot problems, discuss any lack of adherence detected in the device usage data (from the device App), encourage adherence, and assess AEs
DAILY ASSESSMENTS (Week 3, Week 6)
Daily diary of CIPN Symptom Inventory and rescue pain medication consumption
6
3
END OF STUDY VISIT (Week 6)
Same outcomes as baseline (minus Expectation Questionnaire) plus General Impression of Neuropathy, General Impression of Activity, Qualitative Feedback Questionnaire, Blinding Questionnaire, Changes in concomitant pain medications, Device usage data (downloaded from the device)v
Follow-up phone call (Week 10)
Ask if participants are using the commercial device