

Remote Monitoring and Management of Chemotherapy Induced Peripheral Neuropathy

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

In order to be eligible to participate in this study, an individual must meet all of the following criteria: 1. Age \geq 18. 2. Completion of taxane, platinum, vinca alkaloid-based chemotherapy, bortezomib, thalidomide, lenalidomide, ixazomib, or brentuximab vedotin for cancer in the last 540 days, or ongoing maintenance therapy with bortezomib, thalidomide, lenalidomide or ixazomib for \geq 90 days. 3. Development of CIPN during or within 3 months of the most recently completed chemotherapy or previous neurotoxic chemotherapy for the same malignancy. For patients on ongoing maintenance therapy: Development of CIPN during current neurotoxic chemotherapy with bortezomib, thalidomide, lenalidomide, ixazomib brentuximab vendotin or vincristine. CIPN diagnosis will be based on clinical diagnosis and the Toronto Criteria for Probable Distal Symmetric Polyneuropathy including the upper and lower extremities. The Toronto Criteria for Probable Distal Symmetric Polyneuropathy is defined as a combination of symptoms and signs of neuropathy including: 1. At least 1 (one) of the following neuropathic symptoms: "asleep numbness", prickling or stabbing, burning or aching pain AND 2. At least 1 (one) of the following: decreased distal sensation, or unequivocally decreased or absent ankle reflexes. (59) Clinical Diagnosis: a. Confirmation of CIPN diagnosis by CIPN expert (investigator/co-investigator based on chart review +/- inperson/virtual interview with examination). 4. Presence of at least one positive neuropathic sensory symptom on the NTSS-6 ranked as moderate or severe on the day of screening or in the preceding week based on recall. 5. The ability to speak/ read sufficient English to be able to communicate with study NP over the phone, utilize the App, website and phone tree (all of which are only available in English).

Exclusion Criteria:

An individual who meets any of the following criteria will be excluded from participation in this study: 1. Expected treatment with another neurotoxic chemotherapy within the 13 week overall study duration (For example, platinum, taxane, vinca alkaloid, thalidomide, brentuximab vedotin or related drug, or arsenic trioxide. This exclusion does not apply to continuation of treatment for patients on maintenance therapy as described in the inclusion criteria). 2. Presence of a neurological problem that would confound CIPN assessment (lumbar or cervical radiculopathy, or pre-existing neuropathy from another cause such as diabetes). 3. Currently receiving treatment at a pain clinic specifically for CIPN pain. 4. Concurrent participation in a different CIPN or pain treatment trial. 5. For women of childbearing potential: Current pregnancy 6. For women of childbearing potential: Unwillingness to use and acceptable form of birth control for the duration of the study. Acceptable forms of birth control include long acting implantable contraception (ie IUDs, Nexplanon), Oral contraception pills, contraception injections, or strict abstinence if it is part of the subject's current lifestyle.

Conditions & Interventions

Interventions:

OTHER: Symptom Care at Home with NP follow up

Conditions:

Chemotherapy-induced Peripheral Neuropathy

More Information

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Principal Investigator:

Phase: NA

IRB

Number:

System ID: NCT04763356

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