PACIFIC NEUROSCIENCE INSTITUTE℠

JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

CIPN: Chemotherapy-Induced Peripheral Neuropathy

Official Title: An Observational Study of Memantine XR (extended release) and Pregabalin Combination Therapy in Chemotherapy-Induced Peripheral Neuropathy (CIPN)

The primary purpose of this study is to assess the efficacy of memantine XR and pregabalin in reducing neuropathic pain in patients with chemotherapy-induced peripheral neuropathy (CIPN) caused by prior treatment with any chemotherapy as measured by the Brief Pain Inventory- Short Form (BPI-SF)

CIPN is difficult to treat due to the complex pathophysiologic mechanisms involved, making a single agent unlikely to be effective. Memantine XR and Pregabalin both work in different pathways. We predict that their synergistic effects will ease pain of peripheral neuropathy better than either alone .

Memantine XR is an amantadine derivative that blocks excessive NMDA receptor activity without disrupting normal activity by acting as a low affinity, open channel blocker. In a preclinical study, pre-surgical administration of memantine XR prevented neuropathic pain development and cognition dysfunction.

Pregabalin binds to an alpha-2-delta 1 (a subunit of voltage-gated calcium channels) in the dorsal horn of the spinal cord and in the brain . This results in a reduction of excessive release of excitatory neurotransmitters from only the hyper excited neurons.

Key Inclusion Criteria:

- History of any cancer type treated with chemotherapy
- CIPN due to treatment with any of the following:
  - Cisplatin, Carboplatin, and Oxaliplatin
  - Paclitaxel, Docetaxel, and Cabazitaxel
  - Thalidomide, Lenalidomide, and Pomalidomide
  - Vinblastine, Vincristine, Vinorelbine, and Etoposide
  - Ixabepilone
  - Bortezomib, Carfilzomib
  - Eribulin
- Planning to receive treatment for CIPN with memantine XR and pregabalin
- Must be ≥ 3 months beyond completion of chemotherapy
- Not planning to receive concurrent chemotherapeutic agents during the study period
- Patients receiving analgesics for pain associated with CIPN and those on antidepressant regimens, anticonvulsants, or mexiletine are eligible provided they have been on a stable dose for a specified time

For more information, contact the Neuro-Oncology Clinical Trial Team at:
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