IMPACT: A Clinical Investigation on IMproving Peripheral Neuropathy Induced by Anti-Cancer Drugs with Advanced Compression Technology; A Safety and Efficacy Study

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosed solid tumor cancer, who will receive neo-adjuvant or adjuvant chemotherapy - planned IV treatment with at least 4 cycles of chemotherapy, with no planned treatment pause for surgery - willing to wear the Lilac Glove and Boot devices for the prescribed duration (devices to be fitted before infusion, and worn during infusion and for up to one (1) hours post infusion - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- baseline peripheral neuropathy of any kind - chemotherapy in the previous 1 year - any open wounds, sores, cysts or injury on the hands or on part of the upper arm where the device will be applied or on the feet or part of the lower leg where the device will be applied that may not be healed before chemotherapy starts - untreated or uncontrolled hypertension - poorly controlled diabetes - weight greater than 140 kg (308 pounds) - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Conditions:
Cancer
Keywords:
Neuropathy, cancer, chemotherapy, Clinics and Surgery Center (CSC)

More Information

Description: The purpose of this study is to evaluate the effectiveness of investigational devices (the Lilac Glove and Lilac Boot devices) for the temporary reduction of moderate to severe symptoms of peripheral neuropathy caused by chemotherapy during the treatment of cancer. The Lilac Glove and Lilac Boot devices are designed to keep chemotherapy medication from damaging nerves. The study involves wearing the Lilac Glove and Boot devices on both hands and feet at each treatment session. Participants will be randomly assigned (like the flip of a coin) into one of two treatment groups; the “intervention group” (which means you receive treatment with the therapeutic Lilac devices) or the “control group” (which means you will receive treatment with the sham devices).
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Phase: NA
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