Cancer Research Consortium of West Michigan
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FAST FACTS

S2205, ICE COMPRESS: RANDOMIZED TRIAL OF LIMB CRYOCOMPRESSION VERSUS CONTINUOUS COMPRESSION VERSUS LOW CYCLIC COMPRESSION FOR THE PREVENTION OF TAXANE-INDUCED PERIPHERAL NEUROPATHY

ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a participant to be considered eligible for registration in OPEN. Section 5 may be printed and used to by the site but is not to be uploaded in RAVE (unless specially stated). For each criterion requiring test results and dates, please record this information on the Onstudy Form and submit via Medidata Rave® (see Section14.0). Any potential eligibility issues should be addressed to the SWOG SDMC in Seattle at 206/652-2267 or cancercontrolquestion@crab.org prior to registration.
NCI policy does not allow for waiver of any eligibility criterion (http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm).
In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday 4 weeks later would be considered Day 28. This allows for efficient participant scheduling without exceeding the guidelines. If Day any of the days mentioned in Section 5 fall on a weekend or holiday, the limit may be extended to the next working day.

5.1. Disease Related Criteria

a. Participants must have a diagnosis of a solid tumor malignancy
b. Participants must be planning to begin neoadjuvant or adjuvant therapy with one of the protocol-specified chemotherapy regimens below for a solid tumor malignancy within 3 calendar days after randomization.

• Weekly paclitaxel x 12 consecutive weeks
• Weekly paclitaxel x 12 consecutive weeks + carboplatin (weekly x 12 consecutive weeks or every 3 weeks x 4 consecutive cycles)
• Paclitaxel + carboplatin every 3 weeks x 6 consecutive cycles without chemotherapy pause for surgery
• Docetaxel + carboplatin every 3 weeks x 6 consecutive cycles without chemotherapy pause for surgery

NOTE: For any of the protocol-specified chemotherapy regimens, concurrent targeted therapy with biologic therapy is allowed. Pembrolizumab (or other immune checkpoint inhibitors), trastuzumab and/or pertuzumab, or bevacizumab are allowed.

c. Participants must not have a history of skin or limb metastases.

5.2. Prior/Concurrent Therapy Criteria

a. Participants must not have previously received neurotoxic chemotherapy for any reason (e.g., taxanes, platinum agents, vinca alkaloids, or bortezomib).

5.3. Clinical/Laboratory Criteria

a. Participant must be ≥ 18 years old.
b. Participants must not have pre-existing clinical peripheral neuropathy from any cause.
c. Participants must not have a history of Raynaud's phenomenon, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, post-traumatic cold dystrophy, or peripheral arterial ischemia.
d. Participants must not have any open skin wounds or ulcers of the limbs at the time of randomization.

5.4. Additional Criteria

a. Participants must be offered the opportunity to participate in specimen banking as outlined in Section 15.1. With participant consent, specimens must be collected and submitted via the SWOG Specimen Tracking System as outlined in Section 15.2.
b. Participants must be able to complete Patient-Reported Outcome (PRO) questionnaires in English or Spanish.
NOTE: Participants who need help recording answers on the questionnaires may receive assistance according to the guidelines in Section 15.3c.2.
However, participants with impaired decision-making capabilities are not eligible for this study as participants must be able to communicate responses regarding their neuropathy symptoms for the primary study endpoints, as well as communicate responses related to the study intervention such as tolerability and satisfaction.
c. Participants must;
    1) agree to complete PROs at all scheduled assessments, and
    2) complete the baseline PRO questionnaires within 14 days prior to randomization as outlined in Section 15.3.

5.5. Regulatory Criteria

NOTE: As a part of the OPEN registration process (see Section 13.5 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.

a. Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines.