SWOG CANCER RESEARCH NETWORK

July 15, 2022

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NCI COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) AFFILIATES AND SUBAFFILIATES; CTSU

FROM: SWOG Operations Office (E-mail: S2205@swog.org)

RE: **Symptom Control and Qualify of Life Committee – New Study Coming Soon**

S2205, "ICE COMPRESS: Randomized Trial of L**i**mb **C**ryocompr**e**ssion versus Continuous **Compress**ion versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy." Primary Study Chairs: Drs. Melissa Accordino and Kathryn Pennington.

MEMORANDUM – Invitation to Participate in S2205

UPDATE: The deadline to apply has now been extended to August 3, 2022!

The **S2205** study team is excited to invite sites to apply for participation in **S2205**, "ICE COMPRESS: Randomized Trial of L**i**mb **C**ryocompr**e**ssion versus Continuous **Compress**ion versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy."

We anticipate including 25 Recruitment Centers from the NCORP, MU-NCORP, and NCTN in a randomized controlled trial to evaluate the effectiveness of cryocompression vs. continuous compression vs. low cyclic compression delivered via a novel Paxman device to prevent taxane-induced peripheral neuropathy among patients receiving select taxane-based therapies.

The application process is required for sites wishing to participate in this trial. If you are interested in being considered for the study, please review the Protocol Summary below and complete the application at the link below by **August 3, 2022**.

S2205 Recruitment Center Application: https://www.surveymonkey.com/r/8N6SKMW

The application provides information including study objectives, selection process, Recruitment Center requirements and expectations, patient eligibility criteria, and logistical details of using the Paxman Limb Cryocompression System.

UPDATE: A complete PDF including the information listed above and all application questions for reference before applying is now available at the following link: https://www.dropbox.com/sh/38l13pbbn52qly2/AACvn-FLnasitJ0CUSPXEvW-a?dl=0

For questions or additional information, contact the **S2205** Study Chairs and Team at S2205@swog.org. The Study Chairs will be happy to answer any questions as you are completing your application.

Please note that this study has received NCI concept approval. The protocol is currently under NCI review.

This memorandum serves to notify the NCI, and SWOG Statistics and Data Management Center.

Sincerely,

S2205 Study Chairs and Team

Melissa Accordino, MD, MS
Columbia University Medical Center
Phone: 212/305-1945
Email: mkg2134@cumc.columbia.edu

Kathryn Pennington, MD
University of Washington
Phone: 206/598-8300
Email: katypenn@uw.edu

cc: PROTOCOL & INFORMATION OFFICE
Kathryn Pennington
Charles Loprinzi
Debra Barton
Paxman Coolers Ltd.

S2205 Protocol Summary

(Study Concept NCI Approved, Protocol under NCI Review)

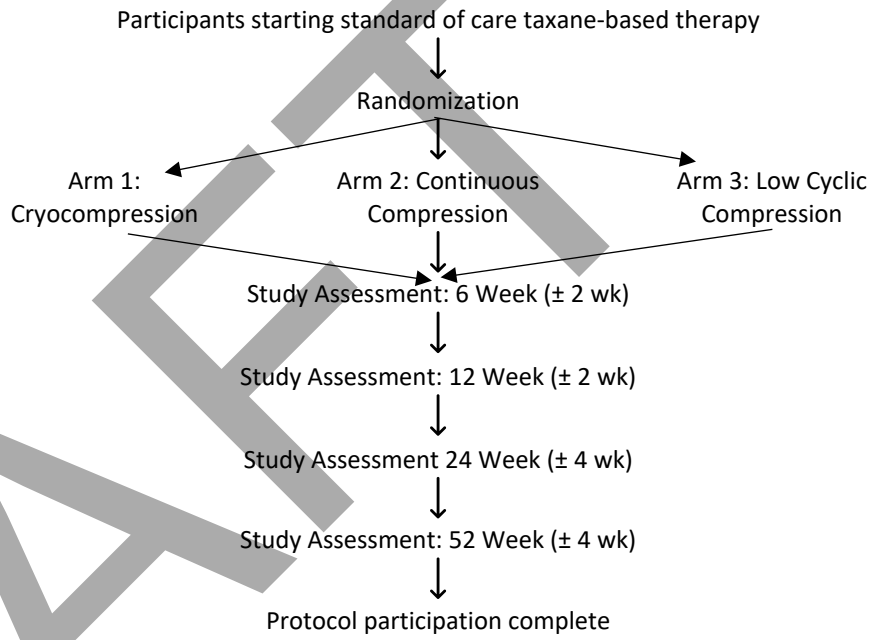
Protocol Summary Version Date: 06/15/2022

S2205, ICE COMPRESS: Randomized Trial of Limb Cryocompression versus Continuous Compression versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy

Participant Eligibility

1. Participants must be planning to receive 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
2. Participants must not have a history of skin or limb metastases.
3. Participants must not have previously received neurotoxic chemotherapy (e.g., taxanes, platinum agents, vinca alkaloids, or bortezomib).
4. Participant must be ≥ 18 years old.
5. Participants must not have pre-existing clinical peripheral neuropathy from any cause.
6. Participants must not have a history of Raynaud's phenomenon, cold agglutinin disease, cryoglobulinemia, cryofibrinogemia, post-traumatic cold dystrophy, or peripheral arterial ischemia.
7. Participants must not have any open skin wounds or ulcers of the limbs at the time of randomization.
8. Participants must be able to complete Patient-Reported Outcome (PRO) questionnaires in English or Spanish, and must: 1) agree to complete PROs at all scheduled assessments, and 2) complete the baseline PRO questionnaires within 14 days prior to randomization.

Schema



Paxman Limb Cryocompression System

One system consists of two devices (one for the arms and one for the legs).

Dimensions of System:
35in (L) x 25in (W) x 45in (H)
Please note that is an approximate as this may be subject to slight modification through redesign.

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Study Calendar

		(± 2 weeks)		(± 4 weeks)	
REQUIRED	**Baseline [F]**	**WK 6 [A]**	**WK 12 [A]**	**WK 24 [A]**	**WK 52 [A]**
TESTS/ASSESSMENTS					
Medical History [E]	X				
Concomitant Medications	X	X	X	X	X
Neuropen (Monofilament and Neurotip) [G]	X	X	X	X	X
128 Hertz Tuning Fork [G]	X	X	X	X	X
Timed Get Up and Go [G]	X	X	X	X	X
NCI-CTCAE [I]	X	X	X	X	X
STUDY INTERVENTION [B]					
Arm 1 – Cryocompression	In conjunction with each taxane chemotherapy infusion				
Arm 2 – Continuous Compression					
Arm 3 – Low Cyclic Compression					
Device Tolerability Assessment [H]					
PATIENT REPORTED OUTCOMES [C]					
EORTC-QLQ-CIPN20	X	X	X	X	X
PROMIS-29 v2.1	X	X	X	X	X
Device Satisfaction and Comfort		X	X		
SPECIMEN SUBMISSION [D]					
Whole Blood for Banking (optional for participants)	X	X	X		
Serum and Plasma for Banking (optional for participants)	X	X	X		

If interested in being considered to participate as an **S2205** Recruitment Center, please apply at https://www.surveymonkey.com/r/8N6SKMW by **August 3, 2022**. For questions, contact S2205@swog.org. Thank you!