

# Clinical trial summary (S2205)

## Cooling and Compression to Prevent Peripheral Neuropathy (Nerve Damage) During Chemotherapy



### What is the purpose of this clinical trial?

This study tests how to prevent a side effect of chemotherapy called peripheral neuropathy. Peripheral neuropathy is a nerve problem that can cause numbness, tingling, or pain in the arms and legs.

This study uses a machine that cools and compresses (applies pressure to) the arms and legs during chemotherapy.

#### **This trial is set up to find out:**

- If cooling, compression, or a combination of both can prevent peripheral neuropathy
- What side effects people have from cooling and compression



### Why is this trial important?

Certain chemotherapy drugs are more likely to cause peripheral neuropathy. Doctors watch for symptoms, and they may give patients smaller doses of chemotherapy if their symptoms get worse. Some patients may need to delay or stop treatment due to worsening symptoms.

Previous research shows that cooling and compression may protect the nerves during chemotherapy. This trial is a chance to learn which approach to these methods works best. It could give patients a new way to prevent peripheral neuropathy without the need to change or delay treatment.



### Who can be in this trial?

This trial is for adults, age 18 or older, with solid tumor cancer.

#### **This trial is for people who:**

- Will receive chemotherapy that uses a certain type of drug known as taxanes (such as paclitaxel or docetaxel)

#### **This trial is not for people who:**

- Have been diagnosed with peripheral neuropathy
- Have Raynaud's Syndrome
- Have peripheral artery ischemia (a condition that reduces blood flow to the arms or legs)

Talk with your doctor to learn more about who can join this study.



## What can I expect during the trial?

The study machine uses Velcro wraps that cover your arms and legs. During chemotherapy treatments, you will receive cooling, compression, or both through the wraps.

To determine which approach you get, a computer will randomly assign you to 1 of 3 study groups. You will get the same approach each time you receive chemotherapy.

	Cooling	Compression (Pressure)
<b>Group 1</b>	The temperature of the wraps will be cool, at 51.8°F (11°C)	Every 5 minutes, the pressure will change between low and medium.
<b>Group 2</b>	No cooling	Steady, medium pressure.
<b>Group 3</b>	No cooling	Every 5 minutes, the pressure will change between low and no pressure.

Your doctor will not have control over which group you will be assigned to. This helps make sure the study results are fair and reliable.



## How long will I be in the trial?

You will be in the study for 1 year. Several times during the study, your doctor will do tests to check your nerves. You will also be asked to complete surveys that ask about your experiences with the study machine and your health. We will try to schedule these parts of the study with your medical visits.



## Are there costs? Will I get paid?

Cooling and compression are provided free in this study. Check with your health care provider and insurance provider to find out what costs will and won't be covered in this study. You will not be paid for joining the study.



## Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and search using the national clinical trial number: **05642611**



## Key information This trial is for adults 18 years or older being

**Full trial title:** ICE COMPRESS: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy

**Protocol number:** S2205

**NCT number:** 05642611

**Trial sponsor:** SWOG Cancer Research Network

**Publishing date:** May 15, 2023

**Thank you!**

When you join a clinical trial, you're moving cancer medicine and patient care forward.