

Nadine M. Tung, M.D.

"This study aims to optimize the amount of chemotherapy that patients with HER2positive breast cancer receive. By giving one chemotherapy drug in combination with anti-HER2 antibodies before surgery, a combination known to be extremely effective, physicians can personalize the amount of therapy needed after surgery. If no cancer remains at surgery, patients will not receive any further chemotherapy, and thus be spared unnecessary toxicity. The trial will evaluate the safety and efficacy of this approach for the patients who have a complete response to this limited chemotherapy."

-Nadine M. Tung, M.D.



Chemotherapy Reduction for Invasive HER2-Positive Breast Cancer

STUDY TITLE: CompassHER2-pCR: Decreasing Chemotherapy for Breast Cancer Patients

After Pre-Surgery Chemo and Targeted Therapy

TRIAL NUMBER: NCT04266249

FOCUS: Treatment

TRIAL PHASE: Phase II (Phase 2)

WHAT HAPPENS IN THIS STUDY?

Paclitaxel (Taxol®) is a taxane <u>chemotherapy</u> drug routinely used to treat breast cancer. Trastuzumab (Herceptin®) and pertuzumab (Perjeta®) are <u>HER2-targeted therapies</u> used to treat HER2-positive breast cancer. The goal of this study is to determine whether treatment with paclitaxel, trastuzumab and pertuzumab before surgery in patients with stage II-IIIa HER2-positive breast cancer eliminates the need for further chemotherapy after surgery (the standard of care) when a pathologic complete response (pCR) is achieved, i.e., no cancer remaining at surgery. This study is referred to as the COMprehensive use of Pathologic response ASSessment to optimize therapy in HER2-positive breast cancer trial (CompassHER2-pCR).

This is a non-randomized trial, which means that all patients receive the same treatment initially. After surgery, the doctor will assign a participant to one of two study groups. Participants who do not have cancer remaining at surgery will be assigned to the first group and receive HER2-targeted therapies, but no further chemotherapy. Participants who have cancer remaining at surgery will be assigned to the second group and receive standard of care chemotherapy and additional HER2-targeted therapy.

ARE YOU ELIGIBLE?

A woman or man over the age of 18 may be eligible if they have been diagnosed with stage II or IIIa HER2-positive breast cancer, have not had any prior treatment for the current breast cancer, have not had a history of previous <u>invasive breast cancer</u> and have not had a history of <u>ductal carcinoma in situ (DCIS)</u> on the same side as the current breast cancer. The status of this study is subject to change. To see the most current information, visit <u>clinicaltrials.gov</u>.

WHAT WILL THIS MEAN FOR PATIENTS?

This study may offer participants the chance to reduce the amount of chemotherapy they receive for HER2-positive breast cancer, and therefore decrease toxicity from treatment. The goal is to optimize the treatment for patients since doctors know that a single taxane chemotherapy drug combined with HER2-targeted therapies is such an effective treatment. Participants will contribute to cancer research that one day may help decrease chemotherapy use for HER2-positive breast cancer without compromising patient outcomes.

WHO DO I CONTACT ABOUT THIS STUDY?

LEAD TRIAL PRINCIPAL INVESTIGATOR AND TRIAL SPONSOR:

- Nadine M. Tung, M.D., Beth Israel Deaconess Medical Center, Boston, Massachusetts, United States.
- ECOG-ACRIN Cancer Research Group, Philadelphia, Pennsylvania, United States.

STUDY LOCATIONS:

This study is offered at multiple sites across the country. See if there is a <u>research site</u> near you or get <u>contact information</u> for a study location.



KOMEN CONNECTION

Nadine M. Tung, M.D., the Principal Investigator (PI) of this study, is a current Komen grantee from Beth Israel Deaconess Medical Center. She is a leading expert on HER2-positive and triple negative breast cancers. Her research interests include identifying increased risks of breast cancer, developing novel therapies to reduce breast cancer risk and finding optimal treatments for patients with breast cancer.

SUSAN G. KOMEN BREAST CARE HELPLINE

For more information about clinical trials, please call our Breast Care Helpline at 1-877 GO KOMEN (1-877-465-6636) or email at clinicaltrialinfo@komen.org to connect with a trained specialist or oncology social worker. Our caring and trained staff provide support, education and resource referrals to help people gain a better understanding of clinical trials. Se habla español.

This information is being provided for education purposes only and does not contain all information related to this clinical study. The study status and eligibility criteria may change. If you are interested in learning if this study is right for you, please reach out to the study coordinator or your doctor for more information.