

## Adding Immunotherapy to Chemotherapy for HER2-Negative Breast Cancer With a Very High Chance of Coming Back

**STUDY TITLE:** Adding Durvalumab to Usual Chemotherapy for People with Early-Stage Breast Cancer and MammaPrint High 2 Test Results  
**TRIAL NUMBER:** NCT06058377  
**FOCUS:** Treatment  
**TRIAL PHASE:** [Phase III \(Phase 3\)](#)

### WHAT HAPPENS IN THIS STUDY?

This study tests treatment for people with early-stage, [hormone receptor-positive \(HR+\), HER2-negative breast cancer](#) that has a very high chance of coming back after treatment. It will test if adding an immunotherapy drug called durvalumab to the usual chemotherapy treatment can help more people get rid of breast cancer completely.

To determine if the cancer has a very high chance of returning, the trial uses a test called MammaPrint. MammaPrint looks at many genes in cancer cells to help predict how the tumor might behave. The test is approved for some HR+, HER2-negative breast cancers. Your doctor will send a small piece of your tumor, removed in a previous biopsy or surgery, to a special lab for this test. This trial is for treating people who receive a High 2 result on MammaPrint testing. If you already had MammaPrint testing, your previous test results will be used for this study.

Study participants will be randomly assigned to receive the usual chemotherapy alone or the usual chemotherapy with durvalumab.

- Usual [chemotherapy](#) for this type of HR+, HER2-negative breast cancer combines 3 drugs: paclitaxel, cyclophosphamide and doxorubicin. These drugs work together to kill the cancer cells, stop them from dividing and stop them from spreading.
- The study drug, durvalumab, works by helping the immune system attack cancer cells and stop them from growing and spreading.

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

### ARE YOU ELIGIBLE?

This trial is for adults, age 18 or older, who have been diagnosed with stage 2 or 3 breast cancer and have not received any previous treatment for the cancer. The cancer must be HR+ and HER2-negative. People with [inflammatory breast cancer](#) may be eligible. A [MammaPrint](#) result of High 2 is required.

### WHAT WILL THIS MEAN FOR PATIENTS?

This study offers eligible participants the chance to receive a new immunotherapy drug, durvalumab. It will help doctors learn if adding this drug to the usual chemotherapy works better to stop the growth of cancer cells than the usual chemotherapy alone. It's a chance to learn if durvalumab can help more people get rid of breast cancer completely. The study may help improve treatment options for future patients.

### WHO DO I CONTACT ABOUT THIS STUDY?

This study is offered at multiple sites in the United States. To see the most up-to-date information about the trial and find [contact information](#) for study locations, visit [clinicaltrials.gov](#).

### LEAD TRIAL PRINCIPAL INVESTIGATOR:

Erin F. Cobain, MD, University of Michigan Rogel Cancer Center, Ann Arbor, MI

### TRIAL SPONSORS:

SWOG Cancer Research Network, San Antonio, TX, and National Cancer Institute, Bethesda, MD

### /// KOMEN CONNECTION

Clinical trials are key to making progress against breast cancer. People who join clinical trials receive high-quality care, and at the same time contribute to research that could help themselves or others. Susan G. Komen wants to help people with breast cancer find — and participate in — clinical trials.

### SUSAN G. KOMEN BREAST CARE HELPLINE

*Do you need help? We're here for you.* The [Komen Patient Care Center](#) is your trusted, go-to source for timely, accurate breast health and breast cancer information, services and resources. Our navigators offer free, personalized support to patients, caregivers and family members, including education, emotional support, help accessing care and financial assistance, information on clinical trials and more. Get connected to a Komen navigator by contacting the Breast Care Helpline at 1-877-465-6636 or email [helpline@komen.org](mailto:helpline@komen.org). 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. To learn if this study is right for you, ask your clinic's study coordinator or your doctor for more information.



Erin F. Cobain, MD

“This study will help determine which patients with HR+, HER2-negative breast cancer might benefit most from a combination of chemotherapy and immunotherapy treatment. We believe that the MammaPrint test may help identify cancer that is more likely to respond to immunotherapy given with the usual chemotherapy. This trial will help us learn if the MammaPrint test can help doctors choose the best treatment option for each person.”

-Erin F. Cobain, MD



Ginny Mason, BSN, RN  
SWOG Patient Advocate

“Tests like MammaPrint are bringing personalized treatment to breast cancer. Trial S2206 takes advantage of this shift, helping to identify which patients might benefit from the addition of immunotherapy to their chemotherapy.”

-Ginny Mason, BSN, RN



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