Clinical trial summary (S2206)

Adding Durvalumab to Usual Chemotherapy for People with Early-Stage Breast Cancer and MammaPrint High 2 Test Results

What is the purpose of this clinical trial?

This study tests treatment for people with early-stage breast cancer that has a high chance of coming back after treatment. It will test adding **an immunotherapy drug called durvalumab** to usual chemotherapy before surgery.

To determine if cancer has a high chance of returning, the trial uses a test called MammaPrint. The MammaPrint test predicts how likely it is the cancer will come back (recur) by looking at many genes in cancer cells. Treatment in the trial is for patients who receive a **High 2** result on MammaPrint testing.

This trial is set up to find out:

- If adding durvalumab to the usual chemotherapy before surgery can lower the chance of breast cancer returning
- If adding durvalumab to the usual chemotherapy helps completely get rid of breast cancer
- What side effects people have from adding durvalumab to usual chemotherapy

Why is this trial important?

Doctors use MammaPrint and similar types of tests to know more about each patient's individual breast cancer. The MammaPrint test is approved by the Food and Drug Administration (FDA) to predict if early-stage breast cancer has a high or low chance of coming back. It isn't approved yet to determine the best treatments for patients.

This trial builds on previous breast cancer research that showed:

- Patients with MammaPrint High 2 test results are more likely to benefit from getting both chemotherapy and immunotherapy.
- Adding durvalumab to chemotherapy works well against other types of breast cancer. (Durvalumab is not FDA-approved yet for treating breast cancer.)

This study is a chance to learn if durvalumab can help more people get rid of breast cancer completely. It may help improve treatment options for future patients.

Who can be in this trial?

This trial is for adults, age 18 or older, with stage 2 or 3 breast cancer.

This trial is for people who:

- Have cancer that is hormone receptor (HR)-positive **and** HER2-negative

This trial is not for people who:

- Have cancer that has spread beyond the breast or nearby lymph nodes
- Already received treatment for breast cancer
- Are pregnant or breastfeeding

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

What treatments will I get?

This study has 2 steps. First, you will have MammaPrint testing. If you already had MammaPrint testing, your previous test results will be used for this study.

Your MammaPrint test result will determine if treatment in the study is an option for you.

Step 1: MammaPrint Testing

Your doctor will send a small piece of your tumor to a special lab for MammaPrint testing. You will **not** need to have another biopsy for this test. They will use a sample of your tumor that was removed in a previous biopsy or surgery.

- If your test result is **High 2**, you may choose to continue in the study for treatment.
- If your test result is *not* High 2, you will not be able to get treatment in this study. Your part in the study will end, and your doctor will talk with you about treatment options that are right for you.

Step 2: Treatment

A computer will randomly assign you to one of 2 study groups:

Group 1:

- Usual chemotherapy (paclitaxel, cyclophosphamide, and doxorubicin)

Group 2:

- Usual chemotherapy plus durvalumab

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?

Treatment in the study will last about 4 and a half months.

After treatment, you will have follow-up visits with the study team until you have been in the study for a total of 10 years.

You can choose to stop treatment and leave the study at any time for any reason.

Are there costs? Will I get paid?

MammaPrint testing and the immunotherapy drug durvalumab are provided free in this study. Ask your health care provider and insurance provider about 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** and search using the national clinical trial number: **NCT06058377**
- For a list of trial locations, visit **swog.org/NCI-S2206**

Key information

Full trial title: Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) Plus Chemotherapy Versus Chemotherapy Alone for Adults with MammaPrint High 2 Risk (MP2) Hormone Receptor (HR) Positive/ Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer

Protocol number: S2206

NCT number: NCT06058377

Trial sponsor: SWOG Cancer Research Network

Publishing date: June 10, 2025

Thank you!

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