

Clinical trial summary (S2511)

Adding Surgery and Radiation to the Usual Treatment for HER2-Positive Breast Cancer That Had Already Spread at Diagnosis



What is the purpose of this clinical trial?

This trial asks if combining different treatment types can help people with HER2-positive breast cancer that spread to as many as 5 areas outside the breast before they were diagnosed.

This is called **HER2-positive de novo oligometastatic breast cancer**.

The study compares 2 options for treating cancer that shrinks with initial (first) drug treatment:



standard drug treatment
+
surgery and radiation therapy

vs.



standard drug treatment alone

HER2-positive breast cancer cells have a protein (called HER2) that can cause them to quickly grow and spread.

This trial is set up to find out:

- For people with cancer that shrinks with initial treatment: Can adding surgery and radiation to standard drug treatment help them live longer?



Why is this trial important?

This is the first large-scale study to test standard drug treatment plus surgery and radiation after initial treatment specifically for HER2-positive de novo oligometastatic breast cancer. Researchers hope the study will lead to better treatment options for people in the future.



Who can be in this trial?

This trial is for adults age 18 or older who have HER2-positive breast cancer.

This trial is for people who:

- Have cancer that had already spread outside the breast at diagnosis to as many as 5 other areas
- Haven't started treatment — or have finished up to 3 cycles of standard drug treatment

This trial is not for people who:

- Have leptomeningeal disease (cancer in the protective coverings of the brain and spinal cord)
- Have more than 5 brain lesions (areas of cancer spread in the brain)



What treatments will I get?

Step 1: Initial Treatment



Everyone in the study will get standard drug treatment for 12 to 24 weeks. This could be one of several drugs or drug combinations that are approved by the U.S. Food and Drug Administration (FDA). You and your doctor will decide which treatment is right for you.



Step 2: Study Treatment

The treatment you get in Step 2 will depend on whether initial treatment shrinks the cancer.



If initial treatment shrinks the cancer in your breast and if the cancer outside your breast does not grow or spread: **A computer will randomly assign you to one of 2 groups of patients, called treatment arms.**

If initial treatment does not shrink the cancer in your breast or if the cancer outside your breast grows or spreads:



Treatment Arm 1:



- You'll have surgery: either a mastectomy (breast removal) or a lumpectomy (removing the cancer without removing the breast)

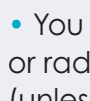


- You'll also have radiation therapy in the breast and the areas where the cancer has spread



- You'll continue standard drug treatment for at least a year — unless the cancer gets worse

Treatment Arm 2:



- You will **not** have surgery or radiation therapy (unless your doctor thinks it would improve your symptoms and make you more comfortable)



- You'll keep getting standard drug treatment for at least a year — unless the cancer gets worse



- You will **not** have surgery or radiation therapy
- You'll keep getting standard drug treatment for as long as you and your doctor agree or until the cancer gets worse

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



How long will I be in the trial?

You'll be in the study for up to 10 years.

After you finish treatment, you'll have visits with your study doctor so they can see how you're doing. You'll have a visit every 6 months until 5 years after you started the study. Then you'll have a visit once a year.

You'll also have imaging scans (like MRI or CT scans) to see if the cancer has gotten worse. You'll have these scans once every 3 or 4 months for about 5 years. After that, if the cancer has not gotten worse, you'll have imaging scans once a year until your part in the study ends.



Are there costs? Will I get paid?

To learn what costs will and won't be covered, talk to your health care provider and insurance provider.

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 the national clinical trial number: **NCT07578116**
- For a list of trial locations, visit swog.org/NCI-S2511



Key information

Protocol number: S2511

NCT number: NCT07578116

Trial sponsor: SWOG Cancer Research Network

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Full trial title: Randomized Phase III Trial Of Multimodality Therapy Versus Standard of Care Systemic Therapy in HER2 Positive (HER2+) de novo (AJCC Stage IV) Oligometastatic Breast Cancer with Response to Initial Chemotherapy

Thank you!

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