

Clinical trial summary (1703)

Testing a New Approach to Monitoring Hormone-Positive, HER2-Negative Breast Cancer That Has Spread



What is the purpose of this clinical trial?

This study will test a new approach for monitoring breast cancer during treatment. The new approach uses blood tests called serum tumor marker (STM) tests. Tumor markers are released into the blood by cancer cells or by other cells in response to cancer cells. STM tests measure the amount of tumor markers in your blood. This information can show your doctor if the cancer is responding to treatment. Researchers will compare this monitoring approach to the usual way of monitoring cancer with imaging scans (such as PET, CT, or MRI scans).

This trial is set up to find out:

- If using STM blood tests to monitor this type of breast cancer is as good as the usual approach of monitoring cancer with regular imaging scans
- If the new approach improves quality of life for patients
- If patients who receive the new approach have less anxiety (“scanxiety”) about imaging scans
- If the new approach lowers healthcare costs



Why is this trial important?

People being treated for breast cancer usually have regular imaging scans to track whether the treatment is helping. But scans can be expensive, and scans make many patients anxious.

If blood tests could be used instead of scans, this approach might improve quality of life for some patients and could lower costs.



Who can be in this trial?

This trial is for adults, age 18 or older, who have breast cancer that has spread to other places in the body outside of the breast (metastatic).

This trial is for people who:

- Have cancer that is hormone-positive. This means the cancer has certain proteins that attach to estrogen or progesterone hormones. Hormone-positive breast cancer can be estrogen receptor positive (ER+), progesterone receptor positive (PR+), or both.
- Have cancer that is HER2-negative. This means the cancer has normal levels of the HER2 protein.
- Have started treatment or plan to start treatment for breast cancer

This trial is not for people who:

- Previously received a different treatment for metastatic breast cancer
- Have cancer that has spread to the brain
- Are pregnant

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



What can I expect during the trial?

You will receive cancer treatment as usual. You and your doctor choose your treatment. To determine how your doctor will monitor the cancer, a computer will randomly assign you to 1 of 2 study groups.

Group 1 (Usual Approach):

- At least every 12 weeks, you will have imaging scans. Your doctor will determine if you also need to have an STM blood test.

Group 2 (New Approach):

- Every 4 to 8 weeks, you will have an STM blood test. The results will determine when you have imaging scans to monitor the cancer.

If your doctor has any concerns for any reason, they can still order imaging scans for you at any time during your care.



How long will I be in the trial?

You will be in the study for up to 6 years. Your study doctor will closely watch your cancer using your assigned approach until your cancer becomes worse or until 6 years after you started the study.



Are there costs? Will I get paid?

You will not be paid for joining the study. Check with your health care provider and insurance provider to find out what costs will and won't be covered in this 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: **03723928**



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

Full trial title: Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) Versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer

Protocol number: S1703

NCT number: 03723928

Trial sponsor: SWOG Cancer Research Network

Publishing date: September 26, 2022

Thank you!

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