

More information can be found on the I-SPY 2 TRIAL website: www.ispy2.org



Please visit the website to find more information about this trial and:

- Commonly asked questions
- Additional things to consider before joining this trial
- MRI scans and the reason they are used
- Biomarkers (tumor characteristics) being studied in this trial
- The way the study selects which treatment will be given to participants and how that information will help other women
- Which clinics are enrolling patients in the I-SPY 2 TRIAL

A Study for Women with Newly Diagnosed Breast Cancer

Will we be able to personalize treatment for breast cancer?

Would you consider joining a trial that tries to answer that question?



This study is sponsored by the Foundation for the National Institutes of Health (FNIH).

Information about the I-SPY 2 TRIAL

Every year about one million Americans join clinical trials to help researchers learn about the benefits and risks of drugs, treatments, and procedures. Clinical trials have helped us find new and effective treatments for breast cancer. Some of these treatments are now the new standard of care for treating women with breast cancer.

There is a new research study for women who have been newly diagnosed with breast cancer and are thinking about getting chemotherapy before surgery, called the I-SPY 2 TRIAL (**I**nterrogation of **S**erial Studies to **P**redict **Y**our **T**herapeutic **R**esponse with **I**maging **A**nd **m**o**L**ecular **A**nalysis **2**). We know that some breast cancers respond well to standard chemotherapy, but some do not. We hope that I-SPY 2 will help us learn if adding investigational drugs with standard chemotherapy will improve the treatment of breast cancer.



In I-SPY 2, participants will be assigned standard chemotherapy with or without investigational drugs based on their own tumor characteristics. The purpose of this trial is to learn more quickly which investigational drugs will be most beneficial for women with certain tumor characteristics. Investigational drugs found to be beneficial will be advanced to future larger studies. The I-SPY 2 researchers will be able to test a variety of drugs with the goal of trying to personalize treatment for breast cancer patients in the future.

Participants' tumors will be closely monitored with multiple MRI scans to see how their tumors respond to chemotherapy treatment. Core biopsies and blood draws will also help identify tumor characteristics that will help researchers learn how individual tumors respond to treatment.

Frequently Asked Questions About this Study

Can I join this study?

All women newly diagnosed with invasive breast cancer who:

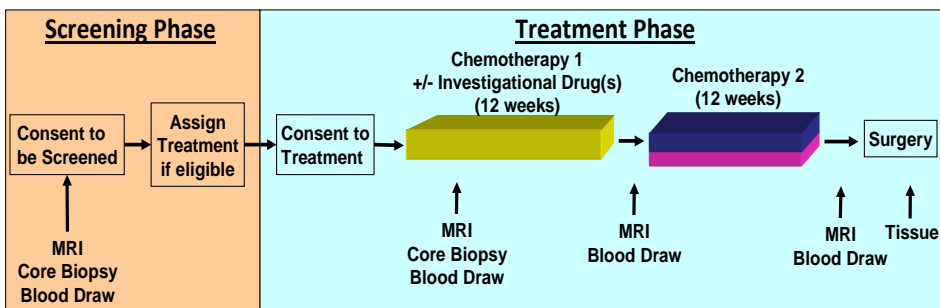
- Are eligible to get chemotherapy before surgery
- Have a 2.5 cm or larger tumor with no cancer elsewhere, except possibly in their lymph nodes
- Are interested in possibly receiving an investigational drug with standard chemotherapy
- Are willing to go undergo extra MRIs, blood draws, and core biopsies for research
- Are not pregnant or breastfeeding

are eligible to be screened for the I-SPY 2 TRIAL.

What happens if I join this study?

There is a two step process to joining this study. First a study doctor and study coordinator will discuss the trial with you. You will be given a screening consent form that outlines the screening study procedures and tests, shown in the diagram below. These procedures and tests are done to find out if you are eligible to join the treatment phase of this study.

If you are found to be eligible for the treatment phase, you will be assigned to receive either standard chemotherapy or standard chemotherapy with an investigational drug before surgery. You will be given a treatment consent form that will explain the drugs you have been assigned to receive.



How is this trial tailored for me?

If you are eligible for the treatment phase of this study, you will be assigned either standard chemotherapy or standard chemotherapy with an investigational drug. You will have an 80% chance of receiving standard chemotherapy with an investigational drug and a 20% chance of receiving just standard chemotherapy. Which treatment you receive will depend on the characteristics of your tumor.

What tumor characteristics will determine which drugs I receive?

Your tumor will be tested for Estrogen Receptor (ER), Progesterone Receptor (PR), and Her2 Receptor levels. This study will also be using an approved research test called MammaPrint. MammaPrint tests the risk of your cancer spreading to another part of your body in the next ten years, if you receive no treatment other than surgery.

If I choose to join, how long will I be in this study?

The screening phase will last about 2 weeks. The treatment phase will last until you have surgery, about 6 months. After completing study treatment and your surgery, you and your doctor will choose what further treatment, if any, you will receive.

What are the costs of being in this study?

The cost of the study procedures and investigational drugs will be covered by the study. The costs of drugs, tests, and procedures that are a part of your regular cancer care will be paid by you or your insurance. Some health insurance companies have rules about joining a research study. Please talk to your insurance company, study doctor and/or coordinator for more details.