More information can be found on the I-SPY 2 TRIAL website:

http://www.gemini-grp.com/ISPYPatientindex.htm

Please visit the website to find more information:

-About this trial and answers to some commonly asked questions about this trial

-About what an MRI scan is and what that means to me

-About what other biomarkers (tumor characteristics) are being studied in this trial

-About how the study selects which treatment I receive and how that helps other women

This study is sponsored by the Foundation for the National Institutes of Health (FNIH), with funding mostly from the FNIH Biomarkers Consortium, a public-private biomedical research partnership of government, industry, academia, and patient advocacy and other non-profit private sector organizations. The Biomarkers Consortium includes the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies. Other partners in the Consortium include the Centers for Medicare & Medicaid Services (CMS) and the Biotechnology Industry Organization (BIO) and its member companies.

A Study for Women with Newly Diagnosed Breast Cancer

Will it be possible to personalize treatment for breast cancer? Would you be interested in joining a

Primary Contact Info:
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E-mail: someone@example.com

Investigation of
Serial studies to
Predict
Your
Therapeutic
Response with
Imaging and
And
moLecular analysis

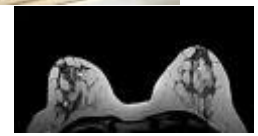
Study Information

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

This brochure provides information about a research study for women who have been newly diagnosed with breast cancer and are thinking about getting chemotherapy before surgery. The trial is called I-SPY 2 TRIAL, **I**nvestigation of **S**erial Studies to **P**redict **Y**our **T**herapeutic **R**esponse with **I**maging **A**nd mo**l**ecular Analysis. Today most women with breast cancer receive standard chemotherapy. We know that some breast cancers respond well to standard chemotherapy, but some breast cancers do not. We hope that I-SPY 2 will help us quickly understand if adding a new drug(s) with standard chemotherapy will improve the treatment of breast cancer.

In I-SPY 2, participants will be assigned standard chemotherapy with or without a new drug(s) based on their own tumor characteristics. This trial is designed to allow researchers to quickly learn which new drug(s) will be most beneficial for women with certain tumor characteristics. New drugs found to be beneficial will be advanced to future larger studies. Those new drugs that are found not to be helpful will be removed from this study. More new drug(s) will enter the trial to help researchers learn from other women who join the study. This will allow the researchers to test more new drugs that could help personalize treatment for breast cancer patients in the future.

Participants will be closely monitored to see how their tumor responds to their chemotherapy treatment using multiple MRI scans. Core biopsies and blood draws will also be obtained to help identify tumor characteristics that will help researchers look for clues about how individual tumors respond to treatment.



Frequently Asked Questions

Who can join this study?

This study is open to all women newly diagnosed with invasive breast caner who:

- Are eligible to get chemotherapy before surgery
- Have a 2.5 cm or larger tumor with cancer no where else in their body, expect possibly in their lymph nodes
- Are interested in receiving new drug(s) with standard chemotherapy
- Are willing to go undergo extra MRI's, blood draws, and core biopsies for research
- Are not pregnant or breastfeeding

What happens if I join this study?

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

Then, if you are found to be eligible for the treatment phase, you will be assigned to receive either standard chemotherapy or standard chemotherapy with a new drug(s) before having surgery. You will be given a treatment consent form that will outline the drug(s) you have been assigned to receive.

This brochure contains a diagram of the all of the study procedures for this trial

Will it cost me anything to be in this study?

The cost of the study procedures and the new drug(s) will be covered by the study. Some health insurance companies have rules about participating in a research study. Please talk to your insurance company, study doctor and/or coordinator for more details.

What new drug(s) will I receive?

Not all women who join this trial will get a new drug(s). If you are eligible for the treatment phase of this study, you will get assigned either standard chemotherapy or standard chemotherapy with a new drug(s). You will have up to an 80% chance of receiving a new drug(s). Which treatment you get will depend on the characteristics of your tumor. Detailed information in the treatment consent form will include information about the specific drug (s) you will get and all of the known risks of that drug(s).

The I-SPY 2 Trial is designed to test multiple new drugs over the course of the trial to quickly learn which new drugs may or may not benefit future patients. This means that the new drug you may have received could leave the trial before the trial is completed.

What tumor characteristics will determine which drug(s) I receive?

Estrogen Receptor (ER), Progesterone Receptor (PR), and Her2/neu (Her2) Receptor levels in your tumor will be tested. The study will also be using an FDA cleared test called MammaPrint. MammaPrint tests the risk of your cancer spreading to another part of your body in the next ten years, if you do not have any treatment.

Investigation of
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Predict
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Therapeutic
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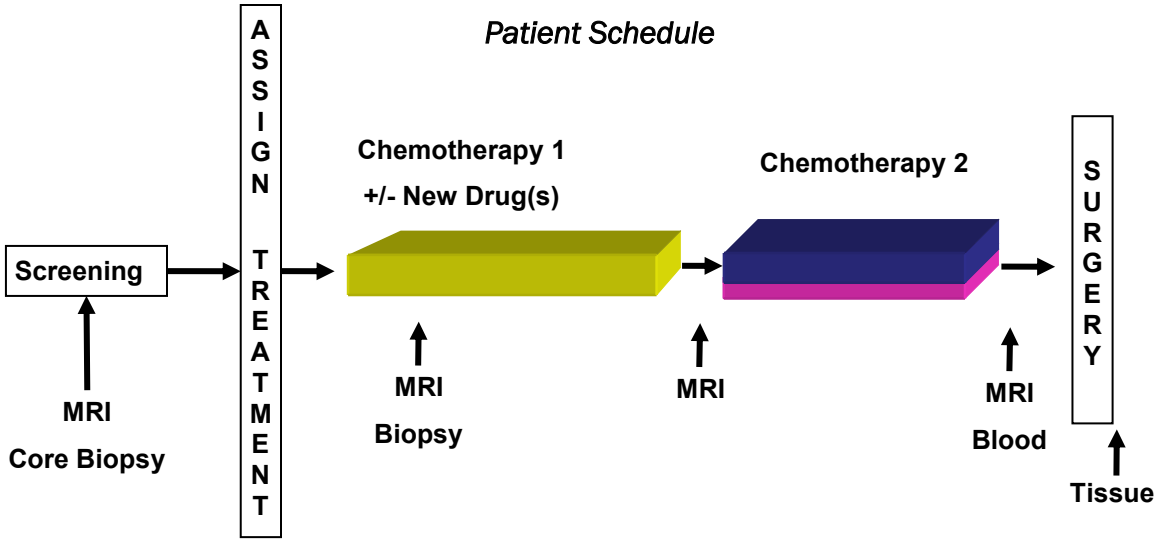
mo**L**ecular analysis

Patient Schedule



NOTES: Patients who are HER+ will receive Herceptin and/or other anti-HER+ drugs

Patients who are ER+ will receive Tamoxifen or and Aromatase Inhibitor after surgery

Patient who need radiation therapy will undergo it after surgery

Patient Advocate Message

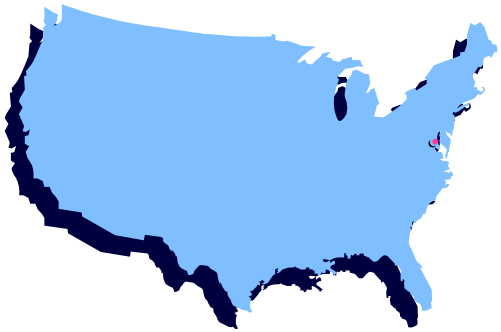
'I am excited about the I-SPY 2 TRIAL because it will study the possible benefit of a number of new drugs for patients, in a relatively short period of time. We now know that the particular type of breast cancer a women has determines which drugs are best suited to treat her cancer. I-SPY 2 will be looking at such targeted therapies to help personalize treatment for breast cancer patients. At the end of the trial we will have a much better idea of who will benefit from what type of treatments. Hopefully, this will spare those women from getting treatments that may not benefit them, and possibly identify those treatments that will hopefully cure their cancer.

Having been diagnosed with breast cancer in 1985, I am concerned that our progress against this disease has not moved more rapidly. One way to help eliminate this disease is through research. While participation in clinical trials is not right for everyone, it can often be a way to get treatment while helping researchers learn more about this disease. The way I-SPY 2 is designed will likely help to identify promising new drugs for women with newly diagnosed breast cancer. Moreover, I-SPY 2 will show that this new way of doing clinical trials, which involves multiple new drugs and assigns drugs to patients based on the biology of their tumors, will allow us to learn more in less time and at a lower cost.'

Jane Perlmutter

Breast Cancer Survivor and Patient Advocate

Where Will This Trail Be Run?



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