I-SPY 2 study speeds up treatment for breast cancer

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A clinical trial that aims to speed up the study of new treatments for certain subtypes of breast cancer now has a designated study site at the Diane O'Connor Thompson Breast Center at the University of Colorado Hospital.

This study, called I-SPY 2, (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis 2) will evaluate which medical treatments are most effective for different types of tumors. So-called "personalized medicine" in cancer is gaining ground as new drugs are developed that target known gene mutations.

In the past, "it could take hundreds of thousands of dollars and several years to study a single drug", says Anthony Elias, MD, breast cancer program director and associate director for clinical research at the University of Colorado Cancer Center (UCCC). "This trial sets up a new kind of mechanism that lets us test multiple drugs at nearly two dozen cancer centers at once, starting with three drugs that have been shown to target known gene abnormalities in common subtypes of breast cancer," Elias says. "Rapid discovery is the name of the game."

UCCC is participating with 20 leading cancer centers in the United States and Canada recruiting and treating patients as part of this large-scale clinical trial aimed at quickly developing new breast cancer drugs. Women who participate will have a new diagnosis of breast cancer and can not have received any previous treatment including surgery. Their breast tumor biopsy is tested using three high-tech biological screening

tools. The results will tell doctors what gene mutations are driving their cancer. If the gene testing results show a tumor it may be less likely to respond to currently available chemotherapy agents, the patient will be invited to enter the drug trial.

"HER2 and triple negative breast cancers are usually bad actors, but some of the ER positive breast cancers can also be aggressive," Elias says. "Each drug we're studying has been shown to work against at least one of these breast cancer subtypes."

About 80 percent of study participants will be randomized to receive a study drug in addition to chemotherapy before surgery and 20 percent will receive standard care, which is chemotherapy before surgery. "For women with this type of breast cancer, chemotherapy before surgery is already the standard for shrinking tumor size and improving surgical outcomes", says Christina Finlayson, MD, surgical oncologist and director of the Diane O'Connor Thompson Breast Center. The study will run for five years and could eventually test dozens of new drugs.

Doctors will be looking for "pathologic complete response", no sign of tumor in the breast tissue and lymph nodes at the time of surgery, as an indication that the study drug made a difference. A complete pathologic response before surgery indicates that the tumor was successfully treated with the medication.

As each woman completes the study treatment, testing of tissue obtained at surgery and information about her outcomes will help researchers decide which treatment will be offered to the next women to join the trial, which is not typically how cancer drug studies work.

"If the first patients respond well to the drug, it's more likely that subsequent patients will get that drug," Elias says. "After a certain number of patients, we can decide if a drug is a success, a failure or

needs further evaluation. We hope we can study three or four drugs every nine months or so, which is about twice as fast as usual. And since the study mechanism will be in place, when we're done testing one drug, we can start studying another drug without creating a whole new trial. That will save years of time and millions of dollars."

The trial data for the first time will be public, which means that breast cancer researchers across the country will have unprecedented information about what the tumors look like before, during and after treatment, plus long-term outcomes. Usually, the drug developer owns the data and keeps it private.

"With this data available for the first time, researchers at UCCC and elsewhere will be able to use it to figure out why people may not get a good response, what pathways are important, what biomarkers are really at play," Elias says. "I-SPY 2 has the power to move the field forward faster than any trial before it. It will create an enormous resource for the future."

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