

PACCT-1 Trial: TAILORx

Fast Facts

Purpose

To use the Oncotype DX Assay to determine which patients with early-stage breast cancer would be more likely to benefit from chemotherapy and reduce the use of chemotherapy in those who are unlikely to benefit from it.

Eligibility

This trial is for patients with newly-diagnosed, early-stage (Stage I or II) breast cancer. The cancer must be estrogen- and/or progesterone-receptor positive and HER2/neu negative, must not have spread to the lymph nodes, and must measure at least one centimeter in size. Some patients who have smaller tumors may be eligible.

Treatment/Procedures

All patients who agree to participate in the trial will have the Oncotype DX test performed on a sample of the tumor that has already been removed. The Oncotype DX results are provided in the form of a Recurrence Score, a number between 0 and 100 which correlates to a specific likelihood of breast cancer recurrence within ten years of initial diagnosis. This does not require an additional biopsy or other procedures. The specimen will be sent to the Genomic Health laboratory for the test. It takes about ten to fourteen days for the doctor to get the result of the test.

Other procedures will include those normally considered part of routine care for breast cancer. Patients will have a history and physical exam by their doctor every three to six months for the first five years, then once a year after that.

Using the results of the Oncotype DX test, patients will be separated into three categories:

- Primary Study Group (Recurrence Score 11-25);
- Secondary Study Group 1 (Recurrence Score 10 or lower); and
- Secondary Study Group 2 (Recurrence Score 26 or higher).

About 40 percent of breast cancer patients fall into the Primary Study Group. Researchers are not sure if patients in this group benefit from chemotherapy. The purpose of the study is to determine whether chemotherapy is beneficial in this group, and if so, which patients benefit.

A Clinical Trial Assigning Individualized Options for Treatment (Rx)

All patients will be asked to donate tissue samples for future research use. Tissue donation is not required to participate in the TAILORx study.

Locations

Visit <http://www.trialcheck.org/cancertrialshelp/cancer-trialshelp.aspx?intAppMode=3&intProtocolUID=22316>, courtesy of the Coalition of Cancer Cooperative Groups to see where the TAILORx study is open.

Sponsor

This trial is being conducted by all of the major National Cancer Institute-funded cooperative groups in the United States. The Eastern Cooperative Oncology Group (ECOG) is coordinating this trial. ECOG is one of the largest cancer research organizations in the United States. It has a network of researchers, physicians, and healthcare professionals at public and private institutions across the country. ECOG conducts clinical trials in all types of adult cancers. It receives funding from the National Cancer Institute (NCI) and other sources. ECOG's goal is to control, effectively treat, and ultimately cure cancer. ECOG provides research results to individuals and the medical community through scientific publications and professional meetings.

More Information

- For more information about ECOG, visit www.ecog.org.
- For more information about cancer and clinical trials, visit:
 - The Coalition of Cancer Cooperative Groups: www.CancerTrialsHelp.org
 - The National Cancer Institute (NCI) Cancer Information Service: 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615, http://cancer.gov/clinical_trials for clinical trial information and http://cancer.gov/cancer_information for more information about cancer.
- For more information about the Oncotype DX Assay, visit: www.oncotypedx.com

