

TAILORx trial finds most women with early breast cancer do not benefit from chemotherapy

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New findings from the groundbreaking Trial Assigning Individualized Options for Treatment (Rx), or TAILORx trial, show no benefit from chemotherapy for 70 percent of women with the most common type of breast cancer. The study found that for women with hormone receptor (HR)-positive, HER2-negative, axillary lymph node–negative breast cancer, treatment with chemotherapy and hormone therapy after surgery is not more beneficial than treatment with hormone therapy alone. The new data, released at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, will help inform treatment decisions for many women with early-stage breast cancer.

The trial was supported by the National Cancer Institute (NCI), part of the National Institutes of Health, and designed and led by the ECOG-ACRIN Cancer Research Group. Findings from the study will be published in *The New England Journal of Medicine*.

"The new results from TAILORx give clinicians high-quality data to inform personalized treatment recommendations for [women](#)," said lead author Joseph A. Sparano, M.D., associate director for clinical research at the Albert Einstein Cancer Center and Montefiore Health System in New York City and vice chair of the ECOG-ACRIN Cancer Research Group. "These data confirm that using a 21-gene expression test to assess the risk of [cancer recurrence](#) can spare women unnecessary treatment if the test indicates that [chemotherapy](#) is not likely to provide

benefit."

TAILORx, a phase 3 clinical trial, opened in 2006 and was designed to provide an evidence-based answer to the question of whether hormone [therapy](#) alone is not inferior to hormone therapy plus chemotherapy. The trial used a molecular test (Oncotype DX Breast Recurrence Score) that assesses the expression of 21 genes associated with [breast cancer](#) recurrence to assign women with early-stage, HR-positive, HER2-negative, axillary lymph node–negative breast cancer to the most appropriate and effective post-operative treatment. The trial enrolled 10,273 women with this type of breast cancer at 1,182 sites in the United States, Australia, Canada, Ireland, New Zealand, and Peru.

When patients enrolled in the trial, their tumors were analyzed using the 21-gene expression test and assigned a risk score (on a scale of 0–100) for cancer recurrence. Based on evidence from earlier trials, women in the trial who had a score in the low-risk range (0–10) received hormone therapy only, and those who had a score in the high-risk range (26 and above) were treated with hormone therapy and chemotherapy.

Women in the trial who had a score in the intermediate range (11–25) were randomly assigned to receive hormone therapy alone or hormone therapy with adjuvant chemotherapy. The goal was to assess whether women who received hormone therapy alone had outcomes that were as good as those among women who received chemotherapy in addition to hormone therapy.

"Until now, we've been able to recommend treatment for women with these cancers at high and low risk of recurrence, but women at intermediate risk have been uncertain about the appropriate strategy to take," said Jeffrey Abrams, M.D., associate director of NCI's Cancer Therapy Evaluation Program. "These findings, showing no benefit from receiving chemotherapy plus hormone therapy for most patients in this

intermediate-risk group, will go a long way to support oncologists and patients in decisions about the best course of treatment."

The researchers found that the primary endpoint of the trial, invasive disease-free survival—the proportion of women who had not died or developed a recurrence or a second primary cancer—was very similar in both groups. Five years after treatment, the rate of invasive disease-free survival was 92.8 percent for those who had hormone therapy alone and 93.1 percent for those who also had chemotherapy. At nine years, the rate was 83.3 percent for those with hormone therapy alone and 84.3 percent for the group that had both therapies. None of these differences were considered statistically significant.

The rates of overall survival were also very similar in the two groups. At five years, the overall survival rate was 98.0 percent for those who received hormone therapy alone and 98.1 percent for those who received both therapies, and at nine years the respective overall survival rates were 93.9 percent and 93.8 percent.

The researchers also found that women with a score of 0-10 had very low recurrence rates with hormone therapy alone at nine years (3 percent). This confirms similar findings from earlier studies. In addition, they found that women with a score of 26-100 had a distant recurrence rate of 13 percent despite receiving both chemotherapy and [hormone therapy](#). This finding indicates the need to develop more effective therapies for women at high risk of recurrence.

According to the authors, the new findings suggest that chemotherapy may be avoided in about 70 percent of women with hormone receptor-positive, HER2-negative, node-negative breast cancer:

- older than 50 and with a recurrence score of 11-25 (45 percent)
- any age with a recurrence score of 0-10 (16 percent)

- 50 years old or younger with a recurrence score of 11-15 (8 percent)

The findings suggest that chemotherapy may be considered for the remaining 30 percent of women with [hormone](#) receptor-positive, HER2-negative, node-negative breast cancer:

- any age with a recurrence score of 26-100 (17 percent)
- 50 years old or younger with a recurrence score of 16-25 (14 percent)

The new results demonstrate that chemotherapy is not beneficial for most women in the intermediate-risk group. This data adds to findings from a TAILORx analysis published in 2015 that provided prospective evidence that the gene expression test could identify women with a low risk of recurrence who could be spared chemotherapy.

There is one caveat to the new findings. When the researchers analyzed premenopausal women and those less than 50 years old at the higher part of the intermediate risk range (16-25) separately, the results showed there may be a small benefit from chemotherapy, and thus these women should consider chemotherapy with their doctor. However, it is unclear if this benefit is due to the effect of chemotherapy or to endocrine suppression caused by chemotherapy-induced menopause.

"Before TAILORx, there was uncertainty about the best treatment for women with a mid-range [score](#) of 11-25 on the Oncotype DX Breast Recurrence Score test. The trial was designed to address this question, and provides a very definitive answer," said Dr. Sparano. "Any woman with early-stage breast cancer 75 years or younger should have the 21-gene expression test and discuss the results with her doctor to guide her decision to the right therapy."

TAILORx was one of the first large-scale [trials](#) to examine a methodology for personalizing cancer treatment. When the trial was activated, the best available genomic profiling data in women with early-stage breast cancer were retrospective.

Provided by ECOG-ACRIN Cancer Research Group

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