

PACCT-1/TAILORx Clinical Trial Results Summary

Trial Assigning Individualized Options for Treatment

What did this trial involve and who was it for?

TAILORx was a groundbreaking study that sought to determine if patients with estrogen receptor-positive (ER+), HER2-negative (HER2-) early breast cancer could safely skip chemotherapy while receiving endocrine therapy. Early breast cancer refers to cancer that has not yet spread beyond the breast to the lymph nodes. Diagnoses of ER+, HER2- early breast cancer account for about one-half of all newly diagnosed breast cancers in the United States each year. The TAILORx study compared the long-term outcomes of patients receiving endocrine therapy alone versus those receiving endocrine therapy in combination with chemotherapy.

The study used a test that looks at the expression of 21 genes associated with breast cancer recurrence (scored on a scale of 0-100), called the Oncotype DX Breast Recurrence Score. Recurrence is when the cancer returns after a period of remission. Study participants were sorted into groups based on their Oncotype DX score: a score of 0-10 was considered low risk, a score of 11-25 was considered intermediate risk, and a score of 25-100 was considered high risk.

A total of 10,273 patients participated in TAILORx at 1,182 sites in the United States, Australia, Canada, Ireland, New Zealand, and Peru.

What are the results?

In 2018, the original study results were published. The findings showed that chemotherapy may be avoided in about 70% of women with hormone receptor-positive, HER2-negative, node-negative breast cancer:

- Older than 50 and with a recurrence score of 11–25
- Any age with a recurrence score of 0–10
- 50 years old or younger with a recurrence score of 11–15

The findings also showed that chemotherapy may be considered for the remaining 30% of women with hormone receptor-positive, HER2-negative, node-negative breast cancer:

- Any age with a recurrence score of 26–100
- 50 years old or younger with a recurrence score of 16–25

The results demonstrated that chemotherapy is not beneficial for most women in the intermediate-risk group.

In 2023, an updated analysis of data from patients still participating in the trial was published:

- The main study findings from 2018 remained unchanged.
- Patients with a low (0-25) recurrence score who were treated with endocrine therapy alone had recurrence rates that were very low on average – less than 1% per year over 12 years.
- For patients with a higher (26-100) recurrence score who were treated with both endocrine therapy and chemotherapy, recurrence rates remained high.
- Black patients were at a higher risk of recurrence in the first 5 years after diagnosis.

What do the results mean for patients?

- TAILORx is a practice-changing study demonstrating that it is safe for intermediate-risk patients with ER+, HER2- early breast cancer to skip chemotherapy. Avoiding treatment that does not provide added benefits is important to prevent unnecessary side effects and healthcare costs.
 - The study offered new information to help providers personalize treatment plans and recommendations for their patients with early breast cancer and different levels of risk.
 - TAILORx will continue to monitor trial participants for long-term outcomes. Data will continue to be collected, analyzed, and published.
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For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: <https://clinicaltrials.gov/study/NCT00310180>
 - ECOG-ACRIN Website: <https://tinyurl.com/TAILORx2018> and <https://tinyurl.com/TAILORx2023>
 - *New England Journal of Medicine* (2018): <https://www.nejm.org/doi/10.1056/NEJMoa1804710>
 - *Cancer Research* (2023 update): <https://doi.org/10.1158/1538-7445.SABCS22-GS1-05>
 - More publications: <https://clinicaltrials.gov/study/NCT00310180#publications>
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About ECOG-ACRIN

This trial was led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN). ECOG-ACRIN is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN is a component of the National Cancer Institute's National Clinical Trials Network. Learn more at www.ecog-acrin.org.

To all the patients that participated in this trial, thank you. Without the involvement of patients like you, this research would not have been conducted.