

[TAILORx | MAC12 trial showed no benefit from chemotherapy for many women with breast cancer](#)

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Clinical trials are not always about finding a new drug that works but sometimes challenge current standards of care that may help spare patients unnecessary treatment.

New results from the groundbreaking “Trial Assigning Individualized Options for Treatment Rx” (TAILORx) breast cancer trial (CCTG MAC.12 in Canada), show no benefit from chemotherapy for 70% of women with the most common form of breast cancer. The study found that for a group of 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 with hormone therapy alone. These results were presented at the [American Society of Clinical Oncology \(ASCO\)](#) annual meeting on June 3, 2018 and simultaneously published in the [New England Journal of Medicine](#).

This landmark international study of 10,273 women was supported by the National Cancer Institute in the US, led by ECOG-ACRIN Cancer Research Group in the US, and coordinated in Canada by the Canadian Cancer Trials Group (CCTG). The trial was designed to use genetic testing to gauge each patient's risk of cancer recurrence. Based on the molecular test used in this trial (Oncotype DX Breast Recurrence Score) a woman's risk of recurrence is classified as low, intermediate, or high.

The study found that 70% of the tumours tested were identified as intermediate risk. Women whose tumours were in this category were randomly assigned to receive hormone therapy alone or hormone therapy with adjuvant chemotherapy. The objective of the study was to assess whether women who received hormone therapy alone had outcomes that were as good as those among women who received chemotherapy as well as hormonal therapy.

"The impact is tremendous," said the study leader, Dr. Joseph Sparano of Montefiore Medical Centre in New York. "Most women in this situation don't need treatment beyond surgery and hormone therapy, and "the rest of them are receiving chemotherapy unnecessarily."

Dr. Lois Shepherd, the CCTG Senior Investigator for this trial noted the tremendous contribution of Canada to this study with 943 women screened for the trial and 838 enrolled. "The findings from MAC. 12, which showed no benefit for many patients receiving both chemotherapy and hormone therapy in the intermediate risk of recurrence category, will be extremely helpful to women and their physicians in making decisions about treatment following surgery. Many women with early-stage breast cancer will be able to safely avoid chemotherapy without compromising their chances of cure."

The study is the largest ever done of breast cancer treatment, and the results are expected to spare up to 70,000 patients a year in the United States and many more elsewhere the ordeal and expense of these drugs.

Media coverage

- CBC - [Many breast cancer patients can skip chemo, big U.S. study finds](#)
- National Post - [Study finds most women with early-stage breast cancer can skip chemo, and some might have been over-treated](#)
- NY Times - [Good News for Women With Breast Cancer: Many Don't Need Chemo](#)

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New England Journal of Medicine Publication

Sparano JA, Gray RJ, Makower DF, Pritchard KI, Albain KS, Hayes DF, Geyer CE, Dees EC, Goetz MP, Olson JA, Lively T, Badve SS, Saphner TJ, Wagner LI, Whelan TJ, Ellis MJ, Paik S, Wood WC, Ravdin PM, Keane MM, Gomez Moreno HL, Reddy PS, Goggins TF, Mayer IA, Brufsky AM, Toppmeyer DL, Kaklamani VG, Berenberg JL, Abrams J, Sledge GW. Adjuvant Chemotherapy Guided by a 21-Gene Expression Assay in Breast Cancer (**ONLINE**). N Engl J Med 2018.

https://www.nejm.org/doi/full/10.1056/NEJMoa1804710?query=featured_home