

Fulvestrant plus anastrozole extends lives of women with advanced HR+ breast cancer

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Women with metastatic hormone receptor-positive breast cancer live longer when they receive a combination of two anti-estrogen drugs, fulvestrant and anastrozole, compared with treatment with anastrozole alone, according to results of a SWOG Cancer Research Network study appearing in the *New England Journal of Medicine*.

These study results provide the most promising evidence to date of a life-extending first line of <u>treatment</u> for the advanced form of hormone receptor-positive <u>breast cancer</u>, which accounts for about two out of every three cases of breast cancer diagnosed in the United States, according to American Cancer Society statistics.

"These results are very exciting," said Rita Mehta, MD, a member SWOG's breast cancer research committee, a clinical professor at the University of California Irvine, and the medical director of the Breast Center at Chao Family Comprehensive Cancer Center. "Women who received fulvestrant, right up front, lived longer based on this new long-term analysis. This is credible evidence that combination endocrine therapy should be considered an option for first-line treatment of advanced hormone receptor-positive breast cancer."

The new results report the final survival outcomes of <u>women</u> who volunteered to participate in S0226, the SWOG trial led by Mehta. Original results, published in the *New England Journal of Medicine* in 2012, showed an unprecedented improvement in two key cancer treatment measures—how long it takes for cancer to progress, known as



<u>progression-free survival</u>, and how long people with cancer live, or overall survival.

Initial results showed that, when women receive an injection of fulvestrant, a hormone treatment, along with doses of <u>anastrozole</u>, an aromatase inhibitor, they had a relative 20 percent increase in progression-free survival and a relative 19 percent increase in overall survival when compared with treatment with anastrozole alone. Anastrozole works by reducing the body's production of estrogen, the hormone that this type of breast cancer needs to grow. Fulvestrant works by disabling the cancer's ability to use estrogen. Mehta thought that these two anti-estrogen actions might be more effective than anastrozole alone, and launched S0226 to test her theory.

Mehta's new results confirm her early ones. The SWOG team followed S0226 volunteers for a median of seven years after starting treatment on the trial, which enrolled 707 postmenopausal women with breast cancer at 73 hospitals, clinics, and cancer centers across the U.S. and Canada. Here's what they learned: When women got the drug combination as their first line of treatment, their lives were extended by eight months compared with women who took anastrozole alone (median overall survival of 50 versus 42 months). In addition, 42 percent of women who got the combination treatment were alive five years after their treatment, compared with 33 percent for women who got anastrozole alone.

What is particularly interesting, Mehta notes, is that patient survival was strongly positive despite the fact that women received lower than normal doses of fulvestrant in the trial—250 mg per month after the first loading dose compared with the typical 500 mg a month. Another important finding: Women who had received no prior hormone treatment before joining S0226 had the best survival outcomes, as did women who had a breast cancer diagnosis more than 10 years prior to joining the trial—regardless of their tamoxifen use.



Finally, Mehta said, the results show that treatment timing matters. About 45 percent of women who got anastrozole only were later treated with fulvestrant when their cancer got worse or spread. But it was the women who received fulvestrant first who had the best outcomes, as measured by both <u>overall survival</u> and progression-free survival.

"Women who are treated with fulvestrant up front live about eight months longer," Mehta said. "That's a lot of extra time to do the things you love with the people you love."

Provided by SWOG

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