

Many Younger Women With Breast Cancer Can Safely Have a Baby

“Primary results of the POSITIVE trial confirm pregnancy can be a realistic objective for women who had an estrogen dependent breast cancer.”

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There is good news for patients with breast cancer who would like to have a baby. A new study published May 3 in the [New England Journal of Medicine](#) found that for young women with hormone receptor-positive breast cancer, pausing endocrine therapy to pursue a pregnancy did not raise the short-term risk that the disease will recur. Additionally, nearly 75% of the participants in the POSITIVE international clinical trial had at least one pregnancy and nearly 65% delivered healthy babies during their hiatus from hormone therapy.

Young women with early-stage hormone receptor positive breast cancer are often treated with endocrine therapy to deprive tumor cells of access to growth-stimulating hormones. Women are advised not to become pregnant while taking endocrine therapy and, for many, the years-long duration of the therapy may extend beyond their childbearing years.

“Fortunately, the vast majority of young women with early-stage breast cancer are going to be cured of their disease,” said the study’s lead author, [Ann Partridge, MD, MPH](#), the founder and director of the Program for Young Adults with Breast Cancer at Dana-Farber Cancer Institute. “However, current treatment guidelines can often deprive women of the chance to start or grow their families. These data from the POSITIVE study show that many of our younger patients can safely pause their endocrine therapy to pursue pregnancy.”

An international team of researchers designed the POSITIVE study (Pregnancy Outcome and Safety of Interrupting Therapy for Women with Endocrine-Responsive Breast Cancer) to examine the safety of temporarily halting endocrine therapy to pursue pregnancy — specifically, whether a pause affects the risk of breast cancer relapse. The study recruited patients in 116 centers across 20 countries on four continents.

“A global collaboration was required to answer this important question as young women with breast cancer around the world were choosing to interrupt their anti-cancer hormonal treatment in order to complete child-bearing without data indicating that this practice would not increase their risk of a breast cancer recurrence,” explained [Richard Gelber, PhD](#) the trial’s Senior Statistician and co-leader of the International Breast Cancer Study Group (IBCSG) Statistical Center. IBCSG

statisticians have collaborated with clinical colleagues world-wide to design, analyze and report practice-changing clinical trial results, which have improved outcomes for patients with early breast cancer.

From December 2014 through December 2019, 516 women aged 42 or younger who desired to become pregnant enrolled in the study, opting to pause endocrine therapy for up to two years to try to get pregnant. Before pausing their treatment, women had completed between 18 and 30 months of endocrine therapy following surgery for breast cancer.

At a median follow-up of 41 months, 44 participants had experienced a recurrence of breast cancer. The three-year rate of recurrence was 8.9%, similar to the 9.2% rate in an external group of patients who had not paused their endocrine therapy.

Of 497 women followed for pregnancy status, 368 (74%) had at least one pregnancy, and 317 (63.8%) had at least one live birth, with a total of 365 babies born. These rates of conception and childbirth were on par with or higher than rates in the general public.

“The primary results of the POSITIVE trial confirm pregnancy can be a realistic objective for women who had an estrogen dependent breast cancer and definitively break the taboo that having a baby can increase the risk of the cancer coming back,” said international study chair Olivia Pagani, MD on behalf of the International Breast Cancer Study Group. “In the last years, clinical research has improved the cure of these women, and with POSITIVE we give them the opportunity to develop life plans and live their life better.”

Trial participants were strongly recommended to resume endocrine therapy after a pregnancy attempt or success. The researchers will continue to follow the study participants to assess recurrence risk over time.

The POSTIVE study was conducted by the International Breast Cancer Study Group, a division of ETOP-IBCSG Partners Foundation, and by the Alliance for Clinical Trials in Oncology in North America, in collaboration with the Breast International Group (BIG), and U.S. National Clinical Trials Network groups. Initial results were reported at the 2022 San Antonio Breast Cancer Symposium.

The researchers are continuing to follow the study participants to assess recurrence risk over time. They noted that the short follow-up to date is a limitation of the POSITIVE study, as HR-positive breast cancer can recur many years after an initial diagnosis.

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