



Press release

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Patients with HR-positive Breast Cancer May Use Fertility Preservation and Assisted Reproductive Technologies Without Increased Risk of Recurrence

Study examined pregnancy and cancer outcomes among patients who paused endocrine therapy to conceive

SAN ANTONIO – Using fertility preservation and/or assisted reproductive technologies (ART) did not adversely impact three-year cancer recurrence rates among patients with hormone receptor (HR)-positive [breast cancer](#) who paused endocrine therapy to become pregnant, according to results from the [POSITIVE](#) trial presented at the [San Antonio Breast Cancer Symposium](#), held December 5-9, 2023.

“With the increasing age of childbearing, it is becoming more likely that women will be diagnosed with breast cancer before starting or completing their families,” said Hatem A. Azim Jr., MD, PhD, an adjunct professor at the School of Medicine and Breast Cancer Center at the Tecnológico de Monterrey in Mexico.

“Many breast cancer patients may opt for fertility preservation prior to starting cancer treatment and/or may use ART to increase their chances of pregnancy,” he added.

Fertility preservation refers to methods intended to maintain the reproductive potential of the patient. Such methods include ovarian stimulation (which entails using hormones to facilitate the retrieval of oocytes) for subsequent cryopreservation (freezing) of oocytes or embryos; cryopreservation of ovarian tissue; and the use of gonadotropin-releasing hormone analogs during chemotherapy to reduce the risk of premature ovarian failure. ART includes various techniques to help the patient become pregnant, such as the transfer of cryopreserved embryos into a patient’s uterus, ovarian stimulation for in vitro fertilization, intrauterine insemination, embryo or egg donation, ovarian tissue transplantation, and clomiphene use.

[Results](#) from the POSITIVE clinical trial presented at last year’s San Antonio Breast Cancer Symposium suggested that patients with HR-positive breast cancer could safely pause endocrine therapy for up to two years to become pregnant without increasing their risk of breast cancer recurrence. However, the safety of conceiving after fertility preservation and/or ART for these patients remains unclear.

“Despite the accumulating evidence, many oncologists and gynecologists are still concerned about the use of fertility preservation or ART methods, particularly those requiring hormones, in patients with HR-positive breast cancer”, said Prof. Olivia Pagani, the international study chair on behalf of the International Breast Cancer Study Group and SAKK member.

To understand the impact of fertility preservation and ART, Azim and colleagues conducted a secondary analysis of outcomes from the POSITIVE trial. Among the 497 evaluable participants who paused endocrine therapy to attempt pregnancy, 368 (74%) became pregnant.

Among the patients who underwent some form of fertility preservation, 179 used embryo or oocyte cryopreservation prior to enrollment in the POSITIVE trial, while 215 used some form of ART to attempt pregnancy. The most commonly used ART was ovarian stimulation for in vitro fertilization and cryopreserved embryo transfer.

The study found that younger age and cryopreserved embryo transfer were the factors most associated with higher chances of pregnancy, with 82.4% of patients who underwent cryopreserved embryo transfer becoming pregnant.

Ovarian stimulation for cryopreservation, which precedes cryopreserved embryo transfer, was not associated with worse disease outcomes: 9.7% of patients who underwent this procedure experienced a breast cancer recurrence within three years compared with 8.7% of those who did not undergo the procedure.

“Participants who underwent cryopreserved embryo transfer during the study had higher pregnancy rates with no apparent short-term detrimental impact on breast cancer outcome,” said Azim.

Additional analyses found that menstrual cycles returned within six months of pausing endocrine therapy in most patients who had amenorrhea at trial entry, and the type of adjuvant endocrine therapy the patient had received had no impact on the time to pregnancy.

Furthermore, the researchers found that younger patients became pregnant in a shorter time. “We found that at two years after enrollment, 80% of women younger than 35 years had a pregnancy compared to 50% of those who were older than 40,” Azim said.

“Our data, from a prospective and controlled study, show that the use of fertility preservation and ART is effective and is not associated with worse short-term breast cancer outcomes. This information, in addition to the primary POSITIVE results, will help improve the way young women with breast cancer are counseled about fertility preservation and pregnancy planning.” said Prof. Pagani.

A limitation of the study is the short follow-up time.

The study is supported and conducted by the ETOP IBCSG Partners Foundation globally, and the Alliance for Clinical Trials in Oncology in North America, in collaboration with the Breast International Group (BIG), the BIG cooperative groups, and the National Clinical Trials Network of the National Cancer Institute (NCI) of the National Institutes of Health (NIH). Globally, the study received support from Baillet Latour Fund and BIG Against Breast Cancer (Belgium); Frontier Science and Technology Research Foundation, Pink Ribbon Switzerland, Swiss Cancer League, San Salvatore Foundation, Rising Tide Foundation, Swiss Group for Clinical Cancer Research, Clinical Cancer Research Foundation of Eastern Switzerland, Ms. Elisabetta Pavesi, Gateway for Cancer Research, Breast Cancer Research Foundation, Roche Diagnostics International, Verein Bärigüf, Swiss Cancer Foundation, Piajoh Fondazione di Famiglia, Gruppo Giovani Pazienti “Anna dai Capelli Corti,” Schweizer Frauenlauf Bern, C&A, and private donors (all in Switzerland); Dutch Cancer Society (the Netherlands); Norwegian Breast Cancer Society and Pink Ribbon (Norway); ELGC K.K. and Pink Ring (Japan); Mr. Yong Seop Lee, Ms. Sun Hee Kang, and Korean Breast Cancer Foundation (South Korea). In North America, the Alliance for Clinical Trials in Oncology, the Eastern Cooperative Oncology Group-American College of Radiology Imaging Network (ECOG-ACRIN), SWOG Cancer Research Network, NRG Oncology, the Canadian Cancer Trials Group received support from the NIH, the Canadian Cancer Society, the Canada Foundation for Innovation, RETHINK Breast Cancer, the Gilson Family Foundation. Azim reports former employment with Pierre Fabre.

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About the San Antonio Breast Cancer Symposium®

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Since 1977, the San Antonio Breast Cancer Symposium® (SABCS®) has been the leading scientific conference for basic scientists, physician-scientists, clinical investigators and breast care providers, and advocates seeking an exchange of new information in experimental biology, etiology, prevention, diagnosis, and therapy of premalignant breast disease and breast cancer. Founded, owned, and operated by [UT Health San Antonio](#), the symposium has grown to a five-day event attended by an international audience of academic investigators and private physicians from over 100 countries to attain information through abstract presentations, panel discussions, research findings, and state-of-the-art educational sessions. UT Health San Antonio, with co-sponsor the [American Association for Cancer Research](#), supports SABCS, which provides education and accessibility to the latest information regarding the prevention, diagnosis, and treatment of premalignant breast cancer and breast disease. For more information on SABCS, visit www.sabcs.org.

About the International Breast Cancer Study Group (IBCSG)

IBCSG as part of ETOP IBCSG Partners Foundation is one of the world's leading groups in breast cancer research. IBCSG pioneers research in combined hormonal therapy and chemotherapy, timing and duration of adjuvant therapies and quality of life of breast cancer patients. The latest generation of clinical trials in the adjuvant setting addresses tailored treatment for subgroups of patients, as we also expand our research into neoadjuvant treatment, chemotherapy and immunotherapy for advanced disease. In addition to clinical trials, ETOP IBCSG Partners Foundation conduct extensive programs in translational research, database studies, quality of life and statistical methodology. The International Breast Cancer Study Group is dedicated to innovative clinical research to improve the prognosis of women with breast cancer. Patients and investigators from six continents cooperate by participating in extensive clinical trials in breast cancer populations. www.etop.ibcsg.org

About the Swiss Group for Clinical Cancer Research (SAKK)

The Swiss Group for Clinical Cancer Research (SAKK) is a non-profit organization that has been conducting patient-oriented clinical cancer studies since 1965. The members of SAKK are the main clinical oncology centers at the cantonal and private hospitals or at the university hospitals. They work with other hospitals and physicians and together form the SAKK network. The Competence Center of SAKK in Bern supports the researching physicians to develop and conduct multicenter and interdisciplinary studies independent of the pharmaceutical industry.