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Study proves: Women with hormone-sensitive breast cancer can have a baby without additional risk

Results from the POSITIVE study, also called BIG Time for Baby, were presented at the 2022 San Antonio Breast Cancer Symposium: Interrupting endocrine treatment to get pregnant can be done without risk of short-term recurrence. The study is sponsored and conducted by the International Breast Cancer Study Group (IBCSG), a division of the ETOP-IBCSG Partners Foundation based in Bern, and by the Alliance for Clinical Trials in Oncology in North America in collaboration with the Breast International Group (BIG). The Swiss Association for Clinical Cancer Trials (SAKK) and its network provided significant support to the research. In Switzerland, 40 patients and 11 hospitals from the SAKK network were involved in this worldwide clinical cancer study.

With an average of more than 6200 new cases per year, breast cancer is the most common cancer in women in Switzerland. It accounts for just under one-third of all new cases of cancer in women. The risk of developing breast cancer in the course of a lifetime is 11.6%. Breast cancer leads to an average of about 1400 deaths per year. The risk of dying from breast cancer for women is 2.4%.¹

About 20% of women with breast cancer are diagnosed in their reproductive years, and for many of these women, fertility and pregnancy are priority concerns. The results of the POSITIVE study, also called BIG Time for Baby, were presented at the 2022 San Antonio Breast Cancer Symposium. They show that young women with breast cancer who paused their endocrine treatment to try to conceive were able to do so safely. The rate of breast cancer recurrence was similar to women who did not pause their treatment, and most of them were able to have and deliver a healthy baby.

Breast cancer in young women

Most young women with early breast cancer have hormone-sensitive, so-called estrogen receptor positive (ER+) disease, meaning the cancer cells are nourished by their own hormones. These women therefore receive endocrine treatment to block natural hormone production, reducing the risk of cancer recurrence. Endocrine therapy can be prescribed for 5-10 years and affects the ovaries, preventing conception during treatment.

¹ Swiss Cancer Report 2021. <https://www.nkrs.ch/assets/files/publications/Krebsbericht2021/1177-2100-de.pdf>

POSITIVE, a global clinical trial - with Swiss participation

From December 2014 to December 2019, 518 women aged 42 or younger who wanted to become pregnant participated in the study and agreed to interrupt endocrine therapy for about two years to try to become pregnant. Before interrupting treatment, the women had completed 18 to 30 months of adjuvant endocrine therapy. The study is sponsored and conducted globally by the International Breast Cancer Study Group (IBCSG), a division of the ETOP IBCSG Partners Foundation based in Bern, and by the Alliance for Clinical Trials in Oncology in North America in collaboration with the Breast International Group (BIG). Patients from 116 hospitals in 20 countries on 4 continents participated in the study. From Switzerland, 40 patients were involved at 11 network hospitals of the Swiss Association for Clinical Cancer Research (SAKK).

Monica Ruggeri, Head of Program for Young Patients at ETOP IBCSG Partners Foundation and coordinator of the POSITIVE trial: **"We are grateful for the unconditional and long-lasting support of SAKK, to the recruitment of patients through its network in Switzerland. It is only thanks to the efforts of several collaborative research groups, such as SAKK, that we have solid and first in history results to address this important, patient-centered, unmet medical need. In fact, our motto is "one for all and all for one!"**

Prof. Dr. Miklos Pless, President of SAKK: **"For us as an independent research network in clinical cancer research, it is of central importance to be able to contribute with our research to improving the quality of life of cancer patients. Likewise, we believe that collaboration is crucial to finding answers to pressing questions in cancer research. Studies like POSITIVE are only possible because many are working together and sharing ideas and resources to truly improve the lives of breast cancer patients."**

Encouraging initial results

So far, study researchers have found that the percentage of women in whom breast cancer returned (8.9%) was comparable to the percentage of patients who participated in other studies (9.2%).

In addition, conception and birth rates for the total of 365 babies born to the women involved in the study were similar to or higher than in the general population. The study is therefore an encouraging indication for younger women who have been diagnosed with breast cancer and may wish to have children. Still, such decisions should be made in close consultation with medical professionals, as each woman's situation is unique.

Researchers will continue to monitor women participating in the study to assess the risk of breast cancer recurrence over time and to ensure that women complete their endocrine treatment after the planned break.

While the current results are very encouraging, because ER+ breast cancer can recur many years after initial diagnosis, long-term follow-up is essential.

Professor Olivia Pagani, Chair of the IBCSG's international POSITIVE study and SAKK member, said, "The primary results of the POSITIVE study confirm that pregnancy can be a realistic goal for women who have had estrogen-dependent breast cancer, and definitively break the taboo that having a baby can increase the risk of cancer recurrence. Family planning, which was abruptly interrupted by the disease, can be safely resumed. I am immensely happy that with this study we can spread a positive message and take away a major concern of women affected by cancer - the question, "Can I start a family?"

Contact

For questions and further information, please contact Ms. Sarah Nyffeler, Head Marketing, Communication, Fundraising, at +41 31 389 91 91 or media@sakk.ch.

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.

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

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