

Common diabetes drug not effective against early-stage breast cancer, landmark trial reveals

TORONTO (Dec. 7, 2021) – A widely used and inexpensive Type 2 diabetes drug, once hoped to hold enormous promise in treating breast cancer, does not prevent or stop the spread of the most common forms of the disease, according to new findings.

The landmark trial, led by Dr. Pamela Goodwin at Sinai Health and run by the Canadian Cancer Trials Group (CCTG) under the umbrella of the Breast International Group (BIG) network, is the largest of its kind to date, tracking more than 3,600 breast cancer patients from across Canada, the U.S., Switzerland and the U.K.

The randomized, double-blind trial enrolled patients who were treated with two pills a day of either placebo or the diabetes drug metformin. Overall, researchers found the addition of metformin to standard breast cancer treatments did not improve outcomes in the two most common types of breast cancer, hormone receptor-positive or negative.

“The results tell us that metformin is not effective against the most common types of breast cancer and any off-label use for this drug for the treatment of these common types of breast cancer should be stopped,” Dr. Goodwin said.

Dr. Goodwin is a medical oncologist at Sinai Health and a clinician scientist at the Lunenfeld-Tanenbaum Research Institute in Toronto. Dr. Goodwin presented the findings Tuesday at the 2021 San Antonio Breast Cancer Symposium. The results have yet to be peer-reviewed.

While metformin was found not to be effective in treating the most common forms of breast cancer, Dr. Goodwin said the trial found a potentially important result for individuals with a less common but aggressive form of the disease, called HER2-positive breast cancer.

For this subtype of breast cancer, researchers found there was evidence that use of metformin for five years might lead to a reduction in deaths. HER2-positive cancer makes up about 20 per cent of all breast cancers.

“Metformin is not beneficial for use in most common breast cancers, but in the cases of HER2-positive breast cancer, our findings suggest it may be beneficial,” Dr. Goodwin said. “These results need to be replicated in future research before metformin is used as a breast cancer treatment, however, it could provide an additional treatment option for HER2-positive breast cancer.”

Metformin belongs to a class of drugs called biguanides, which are used to treat high blood sugar or diabetes. Previous observational and pre-clinical studies suggested metformin may also reduce the risk of development and increase survival of some cancers, including breast cancer. It was theorized the drug may slow breast cancer growth by improving patient metabolism, notably insulin levels, leading to reduced growth of cancer cells, or that it might impact cancer cells directly.

The results have been submitted for publication. A potential next step will be to prospectively test the impact of metformin in patients with HER2-positive breast cancer in a randomized clinical trial.

The multinational trial was run by CCTG, with support from multiple granting agencies, alongside a large team of scientists, including Dr. Goodwin, Dr. Vuk Stambolic at Princess Margaret Cancer Centre in Toronto, and Drs. Wendy Parulekar and Bingshu Chen at CCTG.

“The CCTG MA.32 trial illustrates the importance of international academic group collaboration to test new treatment approaches with a goal to advance clinical care,” says CCTG Senior Investigator Dr. Wendy Parulekar. “The results of all Phase III trials inform current treatment standards and generate hypotheses to be tested in future

studies. CCTG is grateful to the all the patients and families, health care teams, granting agencies and collaborators who enabled the successful conduct of the trial.”

This research was funded by the Canadian Cancer Society, the National Cancer Institute (US), the Canadian Breast Cancer Foundation, the Breast Cancer Research Foundation, Cancer Research UK, Hold’Em for Life Charity Challenge and Apotex (Canada).

About Sinai Health

Sinai Health is comprised of Mount Sinai Hospital, Hennick Bridgepoint Hospital, the Lunenfeld-Tanenbaum Research Institute and its system partner Circle of Care. It delivers excellent care in hospital, community and home, focusing on the comprehensive needs of people. Sinai Health discovers and translates scientific breakthroughs, pushes boundaries for health solutions and educates future clinical and scientific leaders. Clinical areas of specialization include rehabilitation and complex continuing care, surgery and oncology, urgent and critical care, and women’s and infants’ health. Its Lunenfeld-Tanenbaum Research Institute ranks among the top 10 biomedical research institutes in the world. Sinai Health is a full affiliate of the University of Toronto. www.sinaihealth.ca

About Canadian Cancer Trials Group

[The Canadian Cancer Trials Group \(CCTG\)](#) is a cancer clinical trials research cooperative that runs phase I-III trials to test anti-cancer and supportive therapies at over 85 hospitals and cancer centres across Canada. From the operations centre at [Queen’s University](#), CCTG has supported more than 600 trials enrolling 100,000 patients from 40 countries on 6 continents through a global network of 20,000 investigators and clinical trial staff. CCTG is a national program of the [Canadian Cancer Society](#) and their aim is to improve survival and quality of life for all people with cancer.

About Breast International Group (BIG)

[The Breast International Group \(BIG\)](#) is an international not-for-profit organisation for academic breast cancer research groups from around the world, based in Brussels, Belgium.

Global collaboration is crucial to make significant advances in breast cancer research, reduce unnecessary duplication of effort, share data, contribute to the faster development of better treatments, and increase the likelihood of cures for patients. Therefore, BIG facilitates breast cancer research at international level, by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry.

In 1999, BIG was founded by Dr Martine Piccart and Dr Aron Goldhirsch with the aim to address fragmentation in European breast cancer research. Research groups from other parts of the world rapidly expressed interest in joining BIG and, two decades later, BIG represents a network of over 50 like-minded research groups from around the world. These entities are tied to several thousand specialised hospitals, research centres and world-class breast cancer experts across approximately 70 countries on 6 continents. More than 30 clinical trials are run or are under development under the BIG umbrella at any one time. BIG also works closely with the US National Cancer Institute (NCI) and the National Clinical Trials Network (NCTN), so that together they act as a strong integrating force in the breast cancer research arena.

BIG’s research is supported in part by its philanthropy unit, known as **BIG against breast cancer**. This denomination is used to interact with the general public and donors, and to raise funds for BIG’s purely academic breast cancer trials and research programmes. For more information, visit www.BIGagainstbreastcancer.org

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