

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

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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 <u>breast cancer</u> patients from across Canada, the U.S., Switzerland and the U.K.

The randomized, <u>double-blind trial</u> enrolled patients who were treated with two pills a day of either placebo or the <u>diabetes drug metformin</u>. Overall, researchers found the addition of <u>metformin</u> to standard breast cancer treatments did not improve outcomes in the two most common types of breast cancer, hormone receptor-positive or negative. The findings were published today in the *Journal of the American Medical Association*.

"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," said Dr. Goodwin, a medical oncologist at Sinai Health and a clinician scientist at the Lunenfeld-Tanenbaum Research Institute in Toronto.

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 percent 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 <u>clinical care</u>," said 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."

More information: Pamela Goodwin et al, Effect of Metformin vs Placebo on Invasive Disease–Free Survival in Patients With Breast Cancer, *JAMA* (2022). DOI: 10.1001/jama.2022.6147

Provided by Lunenfeld-Tanenbaum Research Institute

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