

Breast Cancer Vaccine Looks Promising in Early Study

The experimental vaccine trains the immune system to recognize HER2 proteins on breast tumors.

February 2, 2023 By [Liz Highleyman](#)

An experimental vaccine that helps the immune system recognize HER2 proteins expressed on tumors showed promising activity in a Phase I study of patients with locally advanced or metastatic breast cancer, researchers reported in [JAMA Oncology](#).

“Because this was not a randomized clinical trial, the results should be considered preliminary, but the findings are promising enough that the vaccine will now be evaluated in a larger, randomized clinical trial,” Mary Disis, MD, of the University of Washington Medicine Cancer Vaccine Institute, said in a [news release](#).

Disis and colleagues tested a plasmid-based DNA vaccine that trains immune cells to recognize HER2 (also known as ERBB2), a protein that plays a role in cell growth. HER2 is overexpressed on around 20% of breast tumors.

Prior research has shown that breast cancer patients with high levels of HER2-specific T cells are less likely to experience disease recurrence after treatment and have longer overall survival, but only a minority develop adequate HER2 immunity on their own.

The investigational vaccine contains a segment of DNA encoding the intracellular domain of HER2. This portion of HER2 is usually located within cells, hidden from the immune system. After vaccination, the DNA is taken up by cells at the injection site, which then produce the encoded protein and present it for recognition by immune cells. Unlike personalized cancer vaccines that are custom-made using antigens from an individual patient’s tumor, HER2 vaccines would be available off-the-shelf.

This nonrandomized study enrolled 66 women with HER2-positive breast cancer who had received standard treatment. About 60% had Stage III (locally advanced) breast cancer and the rest had Stage IV (metastatic) cancer with either no current evidence of disease or stable disease only in the bones.

All participants received one of three doses (10, 100 or 500 micrograms) of the vaccine, which was

administered via intradermal injection once monthly for three months along with granulocyte-macrophage colony-stimulating factor, a cytokine that promotes immune cell production. There was no placebo or untreated control group. The participants received the vaccine between 2001 and 2010 and followed for about 10 years.

Most women who received the 100 mcg vaccine dose produced HER-2 specific type 1 T cells. Patients who received either the 100 mcg or 500 mcg dose had better responses than those who got the 10 mcg dose. However, people who received the 500 mcg dose had more persistent vaccine DNA at the injection site, and those with persistent DNA at 16 weeks had significantly lower HER2 immunity after completing vaccination.

Although this Phase I trial was not designed to determine whether the vaccine can delay recurrence or prevent disease progression, the researchers noted that the participants fared better than expected for patients Stage III or IV breast cancer. “We’ve now followed these women for 10 years and 80% of them are still alive,” Disis said. What’s more, around 60% had not experience disease progression. Both overall and progression-free survival were highest in the group that received the 100 mcg vaccine dose.

The vaccine was generally safe and well tolerated. Most side effects were mild or moderate—typically redness or swelling at the injection site and flu-like symptoms—and the frequency was comparable in all dose groups.

The next step is a Phase II trial ([NCT03384914](#)), which is currently recruiting participants.

“If the results of the new randomized, controlled Phase II trial of the vaccine are positive, it will be a strong signal for us to rapidly move forward to a definitive Phase III trial,” Disis said. “I have high hopes that we’re close to having a vaccine that can effectively treat patients with breast cancer.”

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