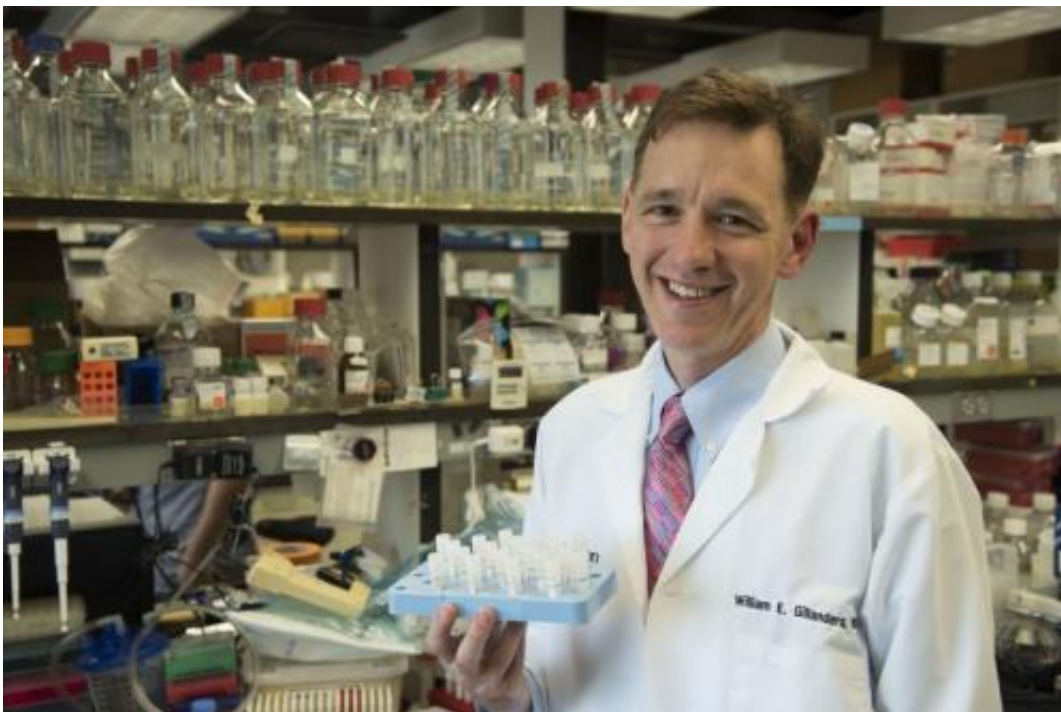


Breast cancer vaccine shows promise in small clinical trial

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A breast cancer vaccine designed by researchers at Washington University School of Medicine in St. Louis is safe in patients with metastatic breast cancer. Preliminary evidence from the small clinical trial, led by William Gillanders, MD, also suggests the vaccine helped slow the cancer's progression. Credit: Robert Boston

A breast cancer vaccine developed at Washington University School of Medicine in St. Louis is safe in patients with metastatic breast cancer, results of an early clinical trial indicate. Preliminary evidence also

suggests that the vaccine primed the patients' immune systems to attack tumor cells and helped slow the cancer's progression.

The study appears Dec. 1 in *Clinical Cancer Research*.

The new [vaccine](#) causes the body's [immune system](#) to home in on a protein called mammaglobin-A, found almost exclusively in breast tissue. The protein's role in healthy tissue is unclear, but breast tumors express it at abnormally high levels, past research has shown.

"Being able to target mammaglobin is exciting because it is expressed broadly in up to 80 percent of breast cancers, but not at meaningful levels in other tissues," said breast cancer surgeon and senior author William E. Gillanders, MD, professor of surgery. "In theory, this means we could treat a large number of breast cancer patients with potentially fewer side effects.

"It's also exciting to see this work progress from identifying the importance of mammaglobin-A, to designing a therapeutic agent, manufacturing it and giving it to patients, all by investigators at Washington University," he added.

The vaccine primes a type of white blood cell, part of the body's adaptive immune system, to seek out and destroy cells with the mammaglobin-A protein. In the smaller proportion of [breast cancer patients](#) whose tumors do not produce mammaglobin-A, this vaccine would not be effective.

In the new study, 14 patients with [metastatic breast cancer](#) that expressed mammaglobin-A were vaccinated. The Phase 1 trial was designed mainly to assess the vaccine's safety. According to the authors, patients experienced few side effects, reporting eight events classified as mild or moderate, including rash, tenderness at the vaccination site and mild flu-

like symptoms. No severe or life-threatening side effects occurred.

Although the trial was designed to test vaccine safety, preliminary evidence indicated the vaccine slowed the cancer's progression, even in patients who tend to have less potent immune systems because of their advanced disease and exposure to chemotherapy.

"Despite the [weakened immune systems](#) in these patients, we did observe a biologic response to the vaccine while analyzing immune cells in their blood samples," said Gillanders, who treats patients at Siteman Cancer Center at Barnes-Jewish Hospital and Washington University. "That's very encouraging. We also saw preliminary evidence of improved outcome, with modestly longer progression-free survival."

Of the 14 patients who received the vaccine, about half showed no progression of their cancer one year after receiving the vaccine. In a similar control group of 12 patients who were not vaccinated, about one-fifth showed no cancer progression at the one-year follow-up. Despite the small sample size, this difference is statistically significant.

Based on results of this study, Gillanders and his colleagues are planning a larger clinical trial to test the vaccine in newly diagnosed [breast cancer](#) patients, who, in theory, should have more robust immune systems than patients who already have undergone extensive cancer therapy.

"If we give the vaccine to patients at the beginning of treatment, the immune systems should not be compromised like in patients with metastatic disease," Gillanders said. "We also will be able to do more informative immune monitoring than we did in this preliminary trial. Now that we have good evidence that the vaccine is safe, we think testing it in newly diagnosed [patients](#) will give us a better idea of the effectiveness of the therapy."

More information: Tiriveedhi V, Tucker N, Herndon J, Li L, Sturmoski M, Ellis M, Ma C, Naughton M, Lockhart AC, Gao F, Fleming T, Goedegebuure P, Mohanakumar T, Gillanders WE. Safety and preliminary evidence of biological efficacy of a mammaglobin-A DNA vaccine in patients with stable metastatic breast cancer. *Clinical Cancer Research*. Dec. 1, 2014.

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