Prevention.

Melanoma Skin Cancer Vaccine From Moderna and Merck Reduces Relapse, **Trial Finds**



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JUMP TO:

- A new vaccine has shown promise in reducing the risk of developing skin
- Phase 2 clinical trial results show the vaccine is 79% effective at preventing cancer in people who are at high risk.
- The vaccine now moves on to Phase 3 clinical trials.

Melanoma is one of the most dangerous forms of skin cancer, and prevention largely involves following safe sun practices (like wearing the best sunscreen and sun protective clothing). But soon there might be an additional tool—a vaccine for skin cancer is in the works. The vaccine comes from Merck and Moderna and is showing promise at lowering the risk of developing melanoma when it's combined with an immunotherapy drug that's already been approved by the Food and Drug Administration (FDA).

People who have had melanoma are at a higher risk of having another one, according to the American Academy of Dermatology (AAD). The risk is greatest within the first five years after treatment. This new vaccine could be a gamechanger for these patients. Phase 2 clinical trial results shared by Merck (one of the companies behind the drug) on Sunday revealed that the vaccine reduced the risk of recurrence or death by 44% in patients who had a high risk of recurrence after having had melanoma.

This clinical trial involved 107 patients at high risk for melanoma who received the vaccine along with Keytruda, an immunotherapy drug that's used to treat a range of cancers, along with 50 patients who were just given Keytruda. Overall, 22.4% of patients had a recurrence of cancer or died within about two years in the vaccine and Keytruda group, while 40% of patients in the Keytruda-only group had a recurrence or died.

After 18 months, the recurrence-free survival rate in patients who received the vaccine and Keytruda was nearly 79% compared to 62% in the Keytruda-only group.

It's worth mentioning that this is an mRNA vaccine (i.e. it uses the same technology as the COVID-19 vaccine). "Today's results provide further encouragement for the potential of mRNA as an individualized neoantigen therapy to positively impact patients with high-risk resected melanoma," said Kyle Holen, M.D., senior vice president and head of development, Therapeutics and Oncology, at Moderna, said in a statement. "The profound observed reduction in the risk of recurrence-free survival suggests this combination may be a novel means of potentially extending the lives of patients with high-risk melanoma."

The treatment has gotten a lot of attention: It <u>earned</u> U.S. breakthrough therapy and European Medicines Agency PRIME scheme designation, which can help speed up development.

But why is a skin cancer vaccine needed and who would actually benefit from this? Here's what you need to know.

How does the vaccine work?

The vaccine, which is currently called mRNA-4157 (V940), uses mRNA technology to target mutations in a patient's cancer while leaving healthy cells alone. The vaccine is designed to prime the patient's immune system so they can have an "anti-tumor response" that's specific to their tumor mutation, Merck explains.

The vaccine is very personalized—it's created after a patient's tumor is analyzed after it's been surgically removed.

The vaccine is also designed to stimulate an immune response with a specific type of T-cell that's based on the mutation of the patient's tumor. (T-cells, in case you're not familiar with them, are a type of white blood cell that help protect the body from infection and may help fight cancer, per the National Cancer Institute.)

Keytruda increases the ability of the body's immune system to help detect and fight the tumor cells. "Keytruda is a type of immunotherapy that helps to prevent cancer cells from hiding from your body's immune system," says board-certified dermatologist Ife J. Rodney, M.D., founding director of Eternal Dermatology Aesthetics and professor of dermatology at Howard University and George Washington University. "The vaccine in combination with the Keytruda leads to a greater immune response on your body's part than the Keytruda alone."

Why is a skin cancer vaccine needed?

There is currently no vaccine to help prevent skin cancer, and experts say that's a problem. "Melanoma is one of the deadliest types of skin cancer. If not detected early, it can spread throughout the body," says <u>Gary Goldenberg, M.D.</u>, a board-certified dermatologist practicing in New York City. "Vaccines for cancer, including melanoma, have been tried for decades. Recently, immunotherapy has improved outcomes of patients with metastatic melanoma. It appears that this new vaccine, when combined with immunotherapy, helps patients by improving survival—this is very exciting."

The vaccine is "promising" for patients who are at high risk of melanoma, Dr. Rodney says. "Anything that can enhance your body's response and prevent more skin cancer formation would be beneficial in this patient population specifically," she says.

But Dr. Rodney says that the results should be "taken with a grain of salt" at this time. For starters, the trial still needs to go through phase 3 and, even then, it would need to be approved by the FDA if the results are positive. There's also this to consider, per Dr. Rodney: "It only shows the patients that are cancer-free for 18 months, which is a relatively short time."

"I'd like to see data from a longer time period," she says

Dr. Goldenberg agrees that the results are "promising" but adds, "these results are early and more data are needed for a more conclusive result."

Skin cancer vaccine side effects

There were a few minor side effects in people who were vaccinated or took the vaccine and Keytruda. According to Merck, those included:

- Fatigue
- Injection site pain
- Chills

When will this vaccine be available?

It's unclear at this point. Merck said in a press release that the vaccine will now be tested in phase 3 clinical trials, but those will take some time to complete. If those results are favorable, it will still need to be approved by the FDA before it's available to the public—and that takes time.

How to lower your risk of skin cancer

The AAD recommends doing the following to lower your risk of developing skin cancer:

- Try to stay in the shade, especially between the hours of 10 a.m. and 2 p.m., when the sun's rays are the strongest.
- Wear UV protectant clothing, like a lightweight and long-sleeved shirt, pants, a wide-brimmed hat, and sunglasses with UV protection.
- Use a broad-spectrum, water-resistant sunscreen with an SPF of 30 or higher.
- Reapply sunscreen every two hours, or after swimming or sweating.
- Be extra cautious when you're near water, snow, and sand since they reflect the sun's rays and can increase your chance of sunburn.
- Avoid tanning beds.
- Do regular skin self-exams and see a board-certified dermatologist if you notice any new or suspicious spots.

Dr. Rodney stresses the importance of using sunscreen—and reapplying as needed. "If you only put it on first thing and don't reapply, you're not protected for the majority of the day," she says.