

Full results show AIDS vaccine is of modest help

October 20 2009, By MARILYNN MARCHIONE , AP Medical Writer

(AP) -- Fresh results from the world's first successful test of an experimental AIDS vaccine confirm that it is only marginally effective and suggest that its protection against HIV infection may wane over time.

Yet the findings are exciting to scientists, who think that blood samples from the trial may show how to make a [vaccine](#) that does a better job.

The results also hint that the vaccine may work better in the general population than in those at higher risk of infection, such as gay men and intravenous drug users. It was the first time an [AIDS](#) vaccine was tested mostly in heterosexuals at average risk, and doctors have long known that how a person is exposed to HIV affects the odds of becoming infected.

"This study becomes a landmark. You can put it on a map and begin to figure out where you go from here," said Col. Jerome Kim, the U.S. Army doctor who co-led the trial.

Last month, [researchers announced that](#) a two-vaccine combination cut the risk of becoming infected with HIV by more than 31 percent in a trial of more than 16,000 volunteers in Thailand.

Full results, published online Tuesday by the [New England Journal of Medicine](#) and presented at a scientific conference in Paris, include two additional analyses that merely suggest the vaccine is beneficial, rather

than providing definitive proof.

That's mostly because so few participants became infected - only 125 people, 10 times less than in previous HIV vaccine trials, said Dr. Anthony Fauci, director the National Institute of Allergy and Infectious Diseases, the study's main sponsor.

Critics had leaked one of the analyses last week, saying it showed the original results may have been a fluke. A California-based AIDS advocacy group criticized study leaders for not giving a fuller picture when they held their news conference last month.

"The bottom line is that those results are real," even though they are not good enough to justify using this vaccine now, said Dr. Alan Bernstein, executive director of the Global HIV Vaccine Enterprise, an alliance of governments, AIDS scientists, the World Health Organization and funders such as the Bill & Melinda Gates Foundation.

"We, for the first time, have evidence of protection, and the nitty gritty (arguments) to me don't matter a damn," Bernstein said.

Other scientists who, like Bernstein, had no role in the trial, agreed.

"It's a consistent story. There seems to be some effect. And I think it is an important study. It redirects the field to look at a different kind of vaccine and different kinds of immune responses" than what have been the focus in the past, said Dr. Lawrence Corey of the University of Washington. He heads the [HIV Vaccine](#) Trials Network, an international group of scientists who test vaccines.

The Thailand Ministry of Public Health conducted this trial, which used vaccines made from strains of HIV common in Thailand. They are ALVAC, made by Sanofi Pasteur, and AIDSVAX, originally developed

by VaxGen Inc. and now held by the nonprofit Global Solutions for Infectious Diseases. The vaccines are not made from whole virus and cannot cause [HIV infection](#).

The combo was tested in HIV-negative Thai men and women ages 18 to 30 at average risk of becoming infected. Half received four doses of ALVAC and two of AIDSVAX over six months; the rest received dummy shots. All were given condoms and counseling, and were followed for three years after vaccination ended.

New infections occurred in 51 of the 8,197 given vaccine and in 74 of the 8,198 who received dummy shots. That worked out to a 31 percent lower risk of infection for the vaccine group.

In a smaller analysis of just the 12,452 participants who received all six shots exactly on schedule, there were 86 infections - 36 in the vaccine group and 50 in those given dummy shots.

Though not a statistically significant trend, the vaccine appeared nearly twice as effective among those at low or moderate risk of becoming infected, versus people who share needles, have contact with prostitutes or engage in other risky behaviors.

"Perhaps the requirements for protection against transmission in low-risk heterosexual persons are considerably different or less stringent," Dr. Raphael Dolin of Beth Israel Deaconess Medical Center in Boston wrote in an editorial published by the medical journal.

On the Net:

New England Journal: www.nejm.org

Vaccine conference: tinyurl.com/d235nn

Study information: www.hivresearch.org/phase3/factsheet.html

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