Broadly Neutralizing Antibodies Cut HIV Infections, but Most Strains Are Unaffected

The new prevention approach shows promise, but it isn't heading to the clinic anytime soon.

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The broadly neutralizing antibody (bnAb) VRC01 had little effect on most strains of HIV—but for those it was active against, new cases fell by 75%. This suggests that combining multiple antibodies could prove more effective.

These are the findings of the Antibody Mediated Prevention (AMP) trials, presented this week at the 4th HIV Research for Prevention virtual conference (HIVR4P).

What this means, according to lead investigator Lawrence Corey, MD, of the Fred Hutchinson Cancer Research Center in Seattle, is that the idea of using antibodies against HIV is sound. But this particular approach won't soon be ready for prime time. First, researchers will need to come up with next-generation antibodies and test them in combinations to prevent HIV.

"This is the first study to demonstrate the concept that bnAbs can prevent acquisition of infection," Corey said during a press conference in advance of the meeting. However, he added, "We're going to need cocktails of antibodies. Maybe that shouldn't be surprising, since we've needed cocktails of drugs [for treatment]."

Clinical trials of broadly neutralizing antibody combinations that could protect against HIV for four to six months are already underway. If successful, Corey said, that could mean that an antibody-based prevention approach could be in the clinic in 18 to 24 months.

"AMP is an exciting proof-of-concept of a new and innovative potential form of HIV prevention," International AIDS Society president Adeeba Kamarulzaman, MBBS, said in a press release. "These studies open an important door to what may one day become yet another important approach to preventing HIV infection."

Study Design and Results

The Phase IIb AMP trials recruited gay and bisexual men, transgender adults and cisgender women all over the world. All told, the two studies included 4,623 HIV-negative participants, and they are

among the most complex studies ever done in the prevention field, Corey said.

The first trial (HVTN 703/HPTN 081) recruited 1,924 cisgender women in sub-Saharan Africa, where HIV subtype C is most common. The second (HVTN 704/HPTN 085) enrolled 2,699 gay and bisexual men and transgender adults in South America, Switzerland and the United States, where subtype B is predominant.

More than half of the gay and bisexual cisgender men and transgender adults were Latino—which makes sense, considering that many came from Peru and Brazil. Only 15% were Black and 32% were white. Among the cisgender women, 98% were Black, likely a result of running the trial in Africa. The median age for cisgender men and transgender participants was 28, and the median age for cisgender women was 26.

The studies evaluated VRC01, a broadly neutralizing antibody derived from blood donated by a person living with HIV, much as doctors now collect convalescent plasma from people who have recovered from COVID-19. The idea is that people who have been exposed to a specific virus develop antibodies to control it. Scientists can modify and multiply those antibodies and use them to prevent or treat infection in others. VRC01 has been studied for HIV treatment, prevention and cure research.

In the AMP trials, participants were randomized to receive a placebo or 10 or 30 milligrams per kilogram of VRC01 via IV infusion—a process similar to receiving an infusion of chemotherapy for cancer treatment. They received 10 infusions administered every eight weeks for nearly two years. Participants were tested for HIV every four weeks.

Corey presented interim results from the two studies at HIVR4P. The results were similar across genders, so he reported combined data. The studies will continue to follow participants for eight more weeks, and final results will be presented later.

The interim data showed that, overall, VRC01 had little effect on HIV acquisition. That's because the antibody is active against only certain strains of HIV, and those strains accounted for just 30% of the circulating virus in the regions where the studies were conducted. VRC01 also didn't prevent transmission of resistant HIV strains that were able to bypass the bnAb and infect participants.

However, in the 30% of cases where people were exposed to VRC01-sensitive strains, the rate of HIV acquisition was 0.20 per 100 person-years among people who received the bnAb, compared with 0.86 per 100 person-years among those who received the placebo. That means that, in this minority of participants, VRC01 was associated with a 75% drop in new infections.

For comparison, daily oral Truvada or Descovy for pre-exposure prophylaxis (PrEP) are around 99% effective when used consistently, and once-monthly cabotegravir injections may be even more effective in real-world use.

VRC01 was well tolerated in both trials. No safety concerns were identified, and adherence was high, Corey reported.

Though not as successful as hoped in these studies, the results are a promising first step, according to Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health, which sponsored the trials.

“These findings establish the concept that passive administration of a broadly neutralizing antibody can prevent acquisition of susceptible HIV strains,” he said in a press release. “Insights gleaned from the AMP studies lay the foundation for future development of long-acting antibody-based HIV prevention tools and, ultimately, a vaccine.”

Corey said he considers the study a success because the researchers were able to identify biomarkers and develop a laboratory test to predict whether an antibody would work against different strains of HIV and how much is needed for protection, providing tools to move the field forward.

Since the AMP studies began, scientists have made progress on optimizing bNAbs to increase the number of HIV strains they can block, how strongly they bind to the virus, how long they last in the body and how efficiently they trigger an immune response against the virus itself and against HIV-infected cells. Potentially, these optimized bNAbs could be combined to develop a highly effective HIV prevention method, according to NIAID.

Corey noted that antibodies are already in use for many diseases, including for prevention and treatment of COVID-19. He added that it might be possible to administer antibodies by subcutaneous or intramuscular injection rather than IV infusion, and the cost is dropping. “I do think they will be economically feasible if they have high efficacy,” he said.

Click here to read the study abstract.
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