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HIV vaccine trial launches in South Africa

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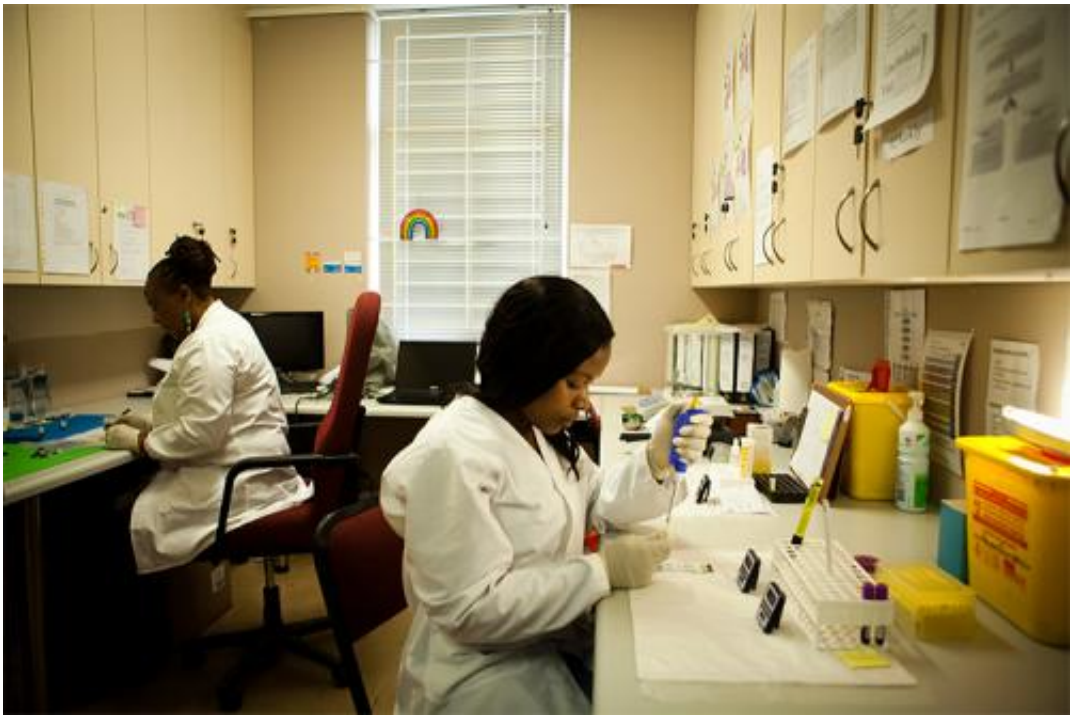

HVTN laboratory staff Nomzamo Tabata (left) and Owethu Mahali process specimens at The Desmond Tutu HIV Foundation in Cape Town, South Africa. Credit: Brooke Auchincloss

A clinical trial called HVTN 100 has been launched in South Africa to study an investigational HIV vaccine regimen for safety and the immune responses it generates in study participants. This experimental vaccine regimen is based on the one tested in the U.S. Military HIV Research Program-led RV144 clinical trial in Thailand—the first study to demonstrate that a vaccine can protect people from HIV infection. The

HVTN 100 vaccine regimen was designed to provide greater protection than the RV144 regimen and has been adapted to the HIV subtype that predominates in southern Africa. The results of the HVTN 100 trial, expected in two years, will help determine whether or not this vaccine regimen will be tested for efficacy in a large future study in South Africa.

"A safe and effective HIV vaccine is essential to reach a timely, sustained end to the HIV/AIDS pandemic," said Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. "The launch of HVTN 100 marks an important step forward in building upon the promising results of the RV144 trial to produce an HIV vaccine that could have a significant public health impact in southern Africa, where the HIV/AIDS pandemic is most pervasive."

NIAID holds responsibility for all operational aspects of the Phase I/II trial, which has a target enrollment of 252 HIV-uninfected heterosexual adults ages 18 to 40. NIAID and The Bill and Melinda Gates Foundation are co-funding the study along with the South African Medical Research Council, and the NIAID-funded HIV Vaccine Trials Network (HVTN) is conducting the trial. Sanofi Pasteur and Novartis Vaccines manufactured the test vaccines for the study.

The HVTN 100 study is part of a larger HIV vaccine research endeavor led by a group called the Pox-Protein Public-Private Partnership, or the P5—a diverse set of public and private organizations, including NIAID, committed to building on the success of RV144. The P5 aims to produce an HIV vaccine that could have a significant public health benefit in southern Africa and to deepen scientists' understanding of the immune responses associated with preventing HIV infection.

The HVTN 100 trial is being led by protocol chair Linda-Gail Bekker,

M.D., Ph.D., deputy director of the Desmond Tutu HIV Centre at the University of Cape Town and chief operating officer of the Desmond Tutu HIV Foundation in South Africa. Protocol co-chair Fatima Laher, M.D., director of the Perinatal HIV Research Unit at Chris Hani Baragwanath Hospital in Soweto, South Africa, is also heading the trial.

"Our country is helping lead the way in HIV prevention research," said Glenda Gray, MBBCH, FCPaeds (SA), president of the South African Medical Research Council and HVTN co-principal investigator. "A safe and effective vaccine is our best hope for stopping new HIV infections and protecting the health of our communities."

The experimental vaccine regimen tested in the RV144 trial was found to be 31.2 percent effective at preventing HIV infection 3.5 years after vaccination, although it appears to have been 60 percent effective one year after vaccination. In the HVTN 100 study, the design and schedule of the RV144 vaccine regimen have been altered to try to increase the magnitude and duration of vaccine-elicited immune responses.

"HVTN 100 builds on the clues we ascertained from RV144 suggesting we could make the vaccine protection stronger and more durable," said Dr. Bekker. "The clinical research will tell us if our hypotheses are correct."

The HVTN 100 vaccine regimen consists of two experimental vaccines: a canarypox-based vaccine called ALVAC-HIV and a gp120 protein subunit vaccine with an adjuvant that enhances the body's immune response. Both ALVAC-HIV (supplied by Sanofi Pasteur) and the protein vaccine (supplied by Novartis Vaccines) have been modified from RV144 to be specific to HIV subtype C, the predominant HIV subtype in southern Africa. In addition, the protein vaccine in HVTN 100 is using a different adjuvant than did RV144 in the hope of generating a more robust immune response. Finally, the HVTN 100

vaccine regimen will include booster shots at the one-year mark in an effort to prolong the early protective effect observed in RV144.

All study participants will receive a total of eight injections over the course of a year. The volunteers will be randomly assigned to receive either the investigational vaccine regimen (210 participants) or a placebo (42 participants).

The safety of HVTN 100 study participants will be closely monitored throughout the trial. In addition, the HVTN 100 study team will routinely counsel study participants on ways to protect themselves from HIV infection.

The P5 is overseeing two separate but related HIV vaccine research programs in southern Africa. The Development Track, of which HVTN 100 is a part, aims to license a subtype C HIV vaccine regimen similar to the one studied in RV144. The Research Track will study new pox-protein vaccine regimens with a variety of adjuvants as part of the search for next-generation HIV vaccine candidates.

"It has been a long road to reach this point," said Dr. Laher. "People in the South African communities where HVTN 100 will take place are excited that this is a critical trial on the path toward finding a safe and effective HIV vaccine."

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