Studies Begin to Test Long-Acting Antibody Infusions for HIV Prevention

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Two large-scale, multiyear studies of infusions of antibodies as pre-exposure prophylaxis (PrEP) against HIV are beginning this spring. The two Phase III, double-blind, placebo-controlled AMP Studies will give intravenous infusions of the broadly neutralizing antibody VRC01 every eight weeks to see whether it is safe, tolerable and effective at preventing HIV among high-risk individuals. The studies are projected to enroll 4,200 adults.

Research has shown that VRC01 blocks up to 90 percent of the world's HIV strains.

The studies may also provide information about what level of broadly neutralizing antibodies a vaccine or other long-acting form of PrEP is needed to protect against HIV over the long term.

One study, called HVTN 703/HPTN 085, has just begun and will operate out of 24 sites in Brazil, Peru and the United States, enrolling 2,700 transgender individuals and men who have sex with men (MSM). The other study, HVTN 703/HPTN 081, will begin later in the spring and will enroll 1,500 sexually active women at 15 sites in sub-Saharan Africa.

In each of the trials, the participants will be randomized to receive a total of 10 intravenous infusions—one given every eight weeks—of VRC01 at a dose of 30 milligrams per kilogram, a dose of 10 mg/kg or a saline solution placebo. After the 10th infusion, the participants will be followed for 20 more weeks.

Results of the trials are expected in 2022.

The participants will undergo testing for HIV every four weeks and at any point that they report possibly having been exposed to the virus. Those who test positive for HIV will remain in the study for follow-up and be referred to medical care for the virus.

All participants will receive HIV prevention counseling, as well as condoms and lubricant. They will receive counseling about and referral for post-exposure prophylaxis (PEP) following a potential exposure to the virus and will also be referred to available local programs through which they can obtain daily oral Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP).

To read a press release about the study, click here.

For a Q&A about the studies, click here.

For information recruitment for the study of MSM and trans individuals, click here.

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