

Study explores potency of antibodies to combat HIV infection

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HIV infecting a human cell. Credit: NIH

Rutgers' New Jersey Medical School's Clinical Research Center (NJMS-

CRC) is participating as a clinical trial site in a novel study that could signal a new way of protecting people from developing HIV infection, the virus that causes AIDS.

The study – known as the AMP study (for Antibody Meditated Prevention) – will determine whether infusing an experimental antibody (VRC01) into HIV-negative men and transgender individuals who have sex with men, will prevent the acquisition of HIV.

"This is landmark study," said Shobha Swaminathan, an infectious disease specialist and the NJMS-CRC site leader. "It is the first study of this magnitude to see whether an antibody infusion can help prevent new HIV infections. If it proves effective, it could potentially pave a way for developing a vaccine for HIV [infection](#)."

Antibodies are one of the natural ways the human body fights infection. The antibody being studied was initially detected in an individual who was able to successfully control HIV infection without taking any medications for HIV. Subsequently, scientists at the NIH were able to model its structure and recreate this antibody in the laboratory.

At the current time, HIV infections can be treated with many medications but only one medication is available to prevent new infections, and it is not always effective due to noncompliance and other issues, Swaminathan said.

HIV continues to be a major global public health issue, though the rate of infection has fallen significantly in recent years. In 2014, gay and [bisexual men](#) accounted for an estimated 83 percent of all new HIV infections among men in the United States, according to the Centers for Disease Control (CDC).

Though the number of new HIV diagnoses fell 19 percent from 2005 to

2014, certain demographic groups showed increases in the infection. For instance, infections among Hispanic/Latino gay and bisexual men rose by 24 percent; among African American men having sex with men (MSM) and bisexual men, infections rose 22 percent from 2005 to 2014. Therefore, it is exciting that this study is available as one HIV prevention option for the high-risk groups (i.e., African American MSM and bisexual men).

NJMS-CRC, the only site in New Jersey conducting the AMP study was selected in part because it is located in Newark, a hot-spot for HIV infection. Essex County, where Newark is located, has the highest proportion (40 percent) of African Americans in New Jersey living with HIV/AIDS.

Beyond indicating whether the antibody VRC01 is likely to prevent HIV infection, the study also will have an important ancillary result, Swaminathan said. Enrollment activities will provide opportunities for high-risk individuals who have not been tested before to both get tested for HIV and also be educated about risk reduction strategies.

"The study is providing ways for Rutgers to effectively partner with and engage the community effectively to ensure a positive impact that will last long after the study is completed," Swaminathan said.

AMP study sites are recruiting a combined 2,700 HIV-negative men and transgender individuals whose sexual partners are [men](#) – the highest-risk demographic for HIV infection – to test the efficacy of VRC01. Those enrolled will either be given intravenous infusions of VRC01 or a placebo every eight weeks for a total of 10 infusions.

Participants will be closely monitored for approximately 22 months for safety and also to determine whether they've remained HIV-negative.

VRC01 was chosen because in laboratory tests the antibody has shown to be effective against 90 percent of HIV-1 isolates that were tested. This broadly neutralizing antibody (bnAb) is unique in that it acts at the site where HIV virus attaches to the host CD4 or T cells. T-cells are white blood cells that play a vital role the human immune system's ability to fight infection and the CD4 cells are the primary target for HIV-1 viruses.

More than 1.2 million people in the United States are living with HIV, and about one in eight don't know it, the CDC says.

"According to CDC estimates, only about 25 percent of people who are HIV-positive have it under control," says Swaminathan. "That's why this study is so important. We have to make an impact on this epidemic. It's one of the major problems facing our cities."

More information: For more information on the study visit www.ampstudy.org

Provided by Rutgers University

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