

Trial of innovative HIV vaccine using mRNA technology enrolls first participant

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The first 12 study participants have been enrolled in a new Phase 1 clinical trial using the messenger ribonucleic acid (mRNA) vaccine technology developed by Moderna. The study evaluates the safety of and immune responses to three different experimental vaccines against HIV. This randomized, open-label trial represents one of the first clinical studies of the use of mRNA vaccine technology against HIV.

The study, HVTN 302, will enroll up to 108 HIV-negative adults. The primary study hypotheses are that the mRNA vaccines will be safe and well-tolerated among HIV-negative people, and will elicit neutralizing antibodies.

The experimental vaccines carry mRNA, a piece of genetic code, delivering instructions to cells for making proteins, in the same way that the mRNA vaccines against COVID-19 instruct the body's cells to make the SARS-CoV-2 spike protein. These instructions show human muscle cells how to make small portions of proteins that resemble parts of HIV, but are not the actual virus. People cannot get HIV from the vaccines. Once human

immune cells have used the instructions, the mRNA is quickly broken down, and does not stay in the body.

"This study will help us to gain a better understanding of how mRNA technology can be employed to help the body make HIV spike proteins in response to a [vaccine](#)," said Dr. William Schief, professor at Scripps Research and Executive Director of Vaccine Design at IAVI's Neutralizing Antibody Center. "The data we obtain will help guide design and clinical testing of a future HIV vaccine and hopefully will expand on the knowledge we have already gained using an mRNA vaccine for COVID-19."

The investigational vaccines are not expected to provide protection from HIV infection, yet the knowledge gained from this study will aid in the future development of an HIV vaccine regimen. Researchers hope to learn whether the immune system will respond to the experimental vaccines by making antibodies and T cells that could fight HIV if a person is ever exposed to the virus in the future. The trial will also build knowledge about how the immune responses to an mRNA vaccine compare to the responses to protein-based vaccines, while helping define the potentials of using mRNA to increase the pace of developing an HIV vaccine.

"With an estimated 1.5 million individuals worldwide acquiring HIV in 2020, it's crucial that a study like this be done," said Dr. Larry Corey, Principal Investigator of the HVTN, which is based at Fred Hutchinson Cancer Research Center. "We have been studying various HIV vaccines for decades and the science continues to progress, especially with the major advancements in the COVID-19 vaccines involving the use of the mRNA technology. Applying this technology to HIV vaccine research is a defining moment for the field."

Provided by Fred Hutchinson Cancer Research
Center

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