

# Study in sub-Saharan Africa evaluates the effectiveness of the COVID-19 vaccine in people living with HIV

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A highly anticipated clinical trial in eight sub-Saharan countries is the first to specifically examine the effectiveness of a COVID-19 vaccine in people living with HIV, including those with poorly controlled infections. It is also the first study to evaluate the effectiveness of vaccines – in this case Moderna mRNA-1273 – against the Omicron variant of SARS-CoV-2, the virus that causes COVID-19.

In addition to studying the effectiveness of COVID-19 mRNA vaccines in people living with HIV, the study's researchers are trying to identify the optimal regimen for this population and how it can vary based on whether a person has previously had COVID-19 or not.

The study is being carried out in East and South Africa – regions of the world that are severely affected by HIV. About 14,000 volunteers are expected to be enrolled at 54 clinical research centers in South Africa, Botswana, Zimbabwe, Eswatini, Malawi, Zambia, Uganda and Kenya, where adult HIV prevalence ranges from 4.5% to 27%.

The study name Ubuntu borrows from the Nguni word, which means “I am because you are” and encompasses the concept of African coexistence and community. It relates to the networking of African nations and their joint efforts to fight HIV and COVID-19 in this region of the continent.

“Sub-Saharan Africa has been hit hard by the COVID-19 pandemic, but access to effective vaccines, particularly mRNA technology, has been very limited,” said Dr. Nigel Garrett, Study Co-Chair and Head of Vaccine and HIV Pathogenesis Research at the Center for the AIDS Research Program in South Africa (CAPRISA). “The Ubuntu study will provide regulatory agencies with safety data and assess correlates of protection from COVID-19 and answer key questions about dosing regimens for mRNA vaccines in people with HIV.”

In order to find these and other answers, around 12,600 HIV-infected people and around 1,400 HIV-negative people are to be included in the study. About 5,000 of the volunteers have previously had COVID-19, which was confirmed by an antibody blood test done when they first enrolled. All participants will receive the Moderna vaccine, but dosages and schedules will vary based on previous SARS-CoV-2 infection. The organizers said study participants living with HIV will have access to optimal HIV treatment throughout the course of the study.

“This region is facing a tremendous amount of HIV,” said Dr. Glenda Gray, senior advisor to the Ubuntu study protocol and president of the South African Medical Research Council (SAMRC). “Although safe and effective vaccines against COVID-19 have been developed, HIV and COVID-19 are on a collision course,” she added. “The impact of COVID-19 on people living with HIV is a continent’s concern, particularly given the recently sequenced variant of Omicron that will fuel South Africa’s fourth wave and more infections worldwide.”

Dr. Philip Kotzé, a lead investigator on the study, said the Ubuntu study would not be possible without the critical involvement of rural communities in southern and eastern Africa. “These communities are disproportionately affected by the twin pandemics of HIV and COVID-19 and now have an unprecedented opportunity to advance science and improve our understanding of the immune response to SARS-CoV-2 in relation to HIV.”

Dr. Larry Corey, principal investigator of the HIV Vaccine Trials Network (HVTN) and the COVID-19 Prevention Network (CoVPN) and co-director of the network’s vaccine testing pipeline, said there are currently no U.S. government-sponsored studies of COVID-19 vaccines, which quantify the effectiveness of the vaccine in a diverse population of HIV-infected people. This study seeks to fill this knowledge gap and determine whether mRNA vaccines are as effective in people with HIV, especially in advanced disease, as they are in HIV-negative ones.

The study is sponsored and funded by the SAMRC, and supported by the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health. Funding is provided by the Department of Health and Human Services (HHS) through the Countermeasures Acceleration Group (CAG).

“Vaccination and treatment are crucial for those at the dual threat of HIV and COVID-19 as they remain at high risk of infection and transmission and could potentially be the source of future variants,” Corey said. “It is imperative that we, as scientists and as a society, step up our global efforts to find and deliver effective vaccines and treatments. This study is an important step in our efforts to reduce the exposure of people living with HIV to COVID-19 “and understand whether current dosage regimens are appropriate.”

The Ubuntu study is led by the NIH’s CoVPN and is based on extensive community engagement protocols developed and successfully implemented by CoVPN and its research partner HVTN. Both networks are headquartered at the Fred Hutchinson Cancer Research Center in Seattle, Washington.

Source:

Fred Hutchinson Cancer Research Center