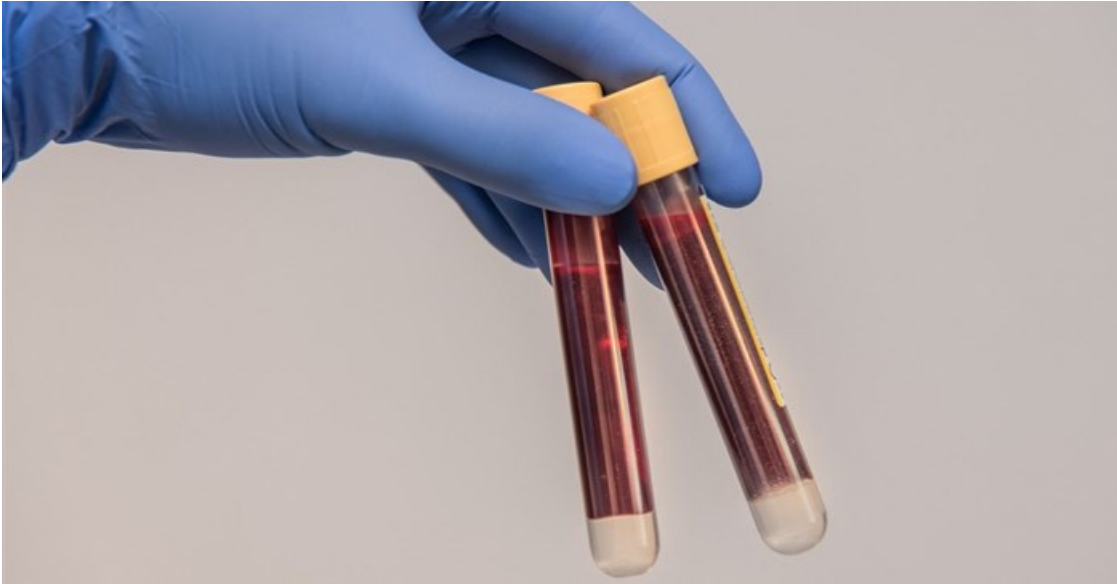


SAMRC sponsors landmark Covid-19 vaccine trial in collaborative bid to combat HIV

A highly anticipated clinical trial in eight sub-Saharan countries is the first to specifically evaluate the efficacy of a Covid-19 vaccine in people living with HIV, including those with poorly controlled infections.



Source: [Rxabay](#)

Sponsored by the South African Medical Research Council (SAMRC), it also is the first study to evaluate the efficacy 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 examining the efficacy of Covid-19 mRNA vaccines in people living with HIV, the study investigators seek to identify the optimal regimen for this population and how it might vary based on whether an individual has previously had Covid-19 or not.

The trial will be conducted in East and Southern Africa – regions of the world that have been highly impacted by HIV. It is expected to enroll about 14,000 volunteers at 54 clinical research sites in South Africa, Botswana, Zimbabwe, Eswatini, Malawi, Zambia, Uganda and Kenya, where adult HIV prevalence ranges from 4.5% to 27%.

United to combat HIV

The study name, Ubuntu, borrows the Nguni word meaning 'I am because you are', and embraces the concept of African co-existence and community. It refers to the interconnectedness of African nations and their collaborative efforts to combat 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, especially mRNA technology, has been very limited,” said Dr. Nigel Garrett, co-chair of the study and head of Vaccine and HIV Pathogenesis Research at the Center for the AIDS Program of Research in South Africa (CAPRISA).

“The Ubuntu trial will provide safety data to regulators and assess correlates of protection from Covid-19, and it will answer important questions on mRNA vaccine dosage regimens among people living with HIV.”



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14,000 to join clinical trial

To find these and other answers, the study is expected to enroll about 12,600 people living with HIV and about 1,400 who are HIV-negative. About 5,000 of the volunteers will have previously had Covid-19, confirmed by an antibody blood test done at initial enrollment. All participants will receive the Moderna vaccine, but dosages and schedules will vary depending on previous SARS-CoV-2 infection.

Organisers said study participants living with HIV will receive access to optimal HIV treatment throughout the course of the trial.

“This region faces a huge HIV burden,” said Dr. Glenda Gray, Ubuntu study protocol lead adviser and president of the South African Medical Research Council (SAMRC). “Although safe and effective vaccines have been developed for Covid-19, HIV and Covid-19 are on a collision course,” she added. “The impact of Covid-19 on people living with HIV is a concern for the continent, particularly in light of the recently-sequenced Omicron variant set to drive further infections in South Africa and globally.”

Dr. Philip Kotzé, one of the lead study investigators, said the Ubuntu study would not be possible without the crucial participation of rural communities across Southern and East Africa. “These communities have been disproportionately impacted by the twin pandemics of HIV and Covid-19, and they now have an unprecedented opportunity to help advance science and improve our understanding of the immune response to SARS-CoV-2 in the context of HIV.”



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US seeks to close knowledge gap

Dr. Larry Corey, principal investigator of both the HIV Vaccine Trials Network (HVTN) and the Covid-19 Prevention Network (CoVPN), and co-leader of the network’s vaccine testing pipeline, said there currently are no US government-sponsored studies of Covid-19 vaccines that quantitate vaccine efficacy among a diverse population of people infected with HIV.

This study seeks to address this knowledge gap and establish whether mRNA vaccines are as effective in people living with HIV, particularly those with advanced disease, as they are in those who are HIV-negative.

US funding and support

The trial is funded by the US government and supported by the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health. Funding originates from the Department of Health and Human Services (HHS) through the Countermeasures Acceleration Group (CAG).

“Vaccination and treatment are critical for those who face the dual threat of HIV and Covid-19, as they remain at high risk of acquisition and transmission, and potentially can be the origin of future variants,” Corey said.



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“It is imperative that we as scientists and as society double-down on global efforts to find and make available effective vaccines and treatments. This study represents an important step forward in our efforts to reduce the burden of Covid-19 among HIV-infected persons and to understand whether current dosage regimens are adequate.”

The Ubuntu study is led by the National Institute of Health's Covid-19 Prevention Network (CoVPN) and modeled on extensive community engagement protocols pioneered and successfully implemented by the CoVPN and its research partner, the HIV Vaccine Trials Network (HVTN). Both networks are headquartered at the Fred Hutchinson Cancer Research Center in Seattle, Washington.

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