Dual Antibodies Did Not Protect Young Women From HIV

A pair of broadly neutralizing antibodies were safe but did not reduce the likelihood of HIV acquisition in a South African trial, likely due to viral resistance.

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Results of the CAPRISA 012c clinical trial of a combination of two broadly neutralizing antibodies to prevent HIV infection in young women in southern Africa announced at IAS in Rio de Janeiro

Young women 15 to 24 years in sub-Saharan African continue to bear the brunt of the HIV epidemic. Researchers from the Centre for the AIDS Programme of Research in South Africa (CAPRISA) today (July 29, 2026) announced the results of a Phase II clinical trial evaluating long-acting broadly neutralizing antibodies (bnAbs) for preventing HIV infection in young women at the 26th International AIDS Conference in Rio de Janeiro, Brazil.

What was studied?

Anti-HIV bnAbs are rare antibodies that are different from the usual strain-specific antibodies that are made routinely by a person who acquires HIV. bnAbs recognize and block many different strains of HIV. CAP256V2LS was developed by a partnership of South African and U.S. scientists following the discovery of this bnAb by CAPRISA in a South African participant, who had enrolled in one of our studies. For the CAPRISA team, this has been a 22-year journey in science, involving clinical studies, laboratory investigations, product development and manufacturing, animal studies and finally in clinical trials.

In combination with VRC07-523LS, a bnAb developed by the Vaccine Research Center of the U.S. National Institutes of Health, the two antibodies combine high potency (the strength to kill HIV) and high breadth (ability to kill a range of different strains of HIV). These bnAbs target conserved regions on the virus's outer envelope ie parts of HIV that are difficult for the virus to change without reducing its ability to survive.

Following the Phase I first-in-human CAPRISA clinical trial of CAP256V2LS, this Phase II double-blinded randomized control trial, evaluated CAP256V2LS and VRC07-523LS administered subcutaneously (under the skin) at 6-monthly intervals in young women. A total of 1023 HIV negative participants were enrolled in South African and Zambia. Participants were enrolled at CAPRISA's urban eThekwini clinic, CAPRISA's Vulindlela rural clinic and the Centre for Infectious

Disease Research in Zambia (CIDRZ). All women were offered HIV prevention services, including pre-exposure prophylaxis (PrEP).

Key findings

A total of 512 women were randomized to receive the bnAbs and 511 to receive the placebo. The study showed that both the bnAbs were safe. The overall HIV incidence rate was 3.0 per 100 women-years in this clinical trial. A total of 39 women acquired HIV infection; 17 in the placebo group and 22 in the bnAb group. There was no statistically significant difference in the HIV incidence rates in women who received the bnAbs and those who received placebo, ie. there was no overall protective benefit.

Unexpectedly, 25 of the 39 viruses from the women who acquired HIV, were resistant to both bnAbs while 12 of the remaining 14 were resistant to one of the two bnAbs. A positive finding was that there was a trend towards protection when the viruses were sensitive to both or one of the two bnAbs compared to when the viruses were resistant to both bnAbs.

The way forward

The ongoing high rates of new HIV infections in young women underscores the importance of enhancing HIV prevention and continuing to develop a vaccine and a cure. The CAPRISA 012C trial is a culmination of 22 years of research — while it has not led to a new HIV prevention product, it provides valuable information to guide further bnAb research. Sensitivity to bnAbs in contemporary circulating viruses will need to be factored into planning future trials of bnAbs.

Quotes:

“The CAPRISA 012C trial highlighted the challenge of viral diversity in HIV, including changes in sensitivity to bnAbs. CAPRISA’s 22-year journey was a move from a complex biomedical prevention concept from the laboratory to field-ready evidence. This trial was made possible by the women who participated in this trial.” — Dr Sharana Mahomed, Site Principal Investigator & Head of HIV Pathogenesis, CAPRISA

“Being part of CAPRISA 012 was more than participation in a clinical trial for CIDRZ and the communities it supports. It was an opportunity to help bring cutting-edge HIV prevention science closer to the young women who need it most and contribute to body of knowledge how broadly neutralizing antibodies can potentially prevent HIV acquisition. I am especially proud that Zambia contributed to this important African-led research effort, helping to generate evidence on innovative, long-acting prevention approaches for adolescent girls and young women.” — Dr Izukanji Sikazwe, Head of HIV, The Global Fund & former CEO CIDRZ

“We congratulate the CAPRISA Team on the historic 22-year translational journey of CAP256 broadly neutralizing antibodies, culminating in the rigorously executed CAPRISA 012 trial on CAP256 + VRC07. These pivotal results will strategically inform the future of global HIV antibody research. As one of the few medical innovations both conceptualised and systematically developed

in Africa, this initiative sets a new benchmark for regional scientific leadership, operating at the highest international clinical and laboratory standards." — Dr Michael Makanga, Executive Director Global Health, EDCTP3

Funding: This trial was funded by the European and Developing Countries Clinical Trials Partnership (EDCTP), the Vaccine Research Center of US NIH and the South African government through its Department of Health and Department of Science, Technology and Innovation through the Medical Research Council (SAMRC) and the National Research Foundation (NRF).

About CAPRISA

CAPRISA's headquarters are located at the Nelson Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa. CAPRISA undertakes research in HIV prevention and Tuberculosis at four clinical research sites in KwaZulu-Natal. Our goal is to undertake globally relevant and locally responsive research that contributes to understanding HIV Pathogenesis, Prevention and Treatment.

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