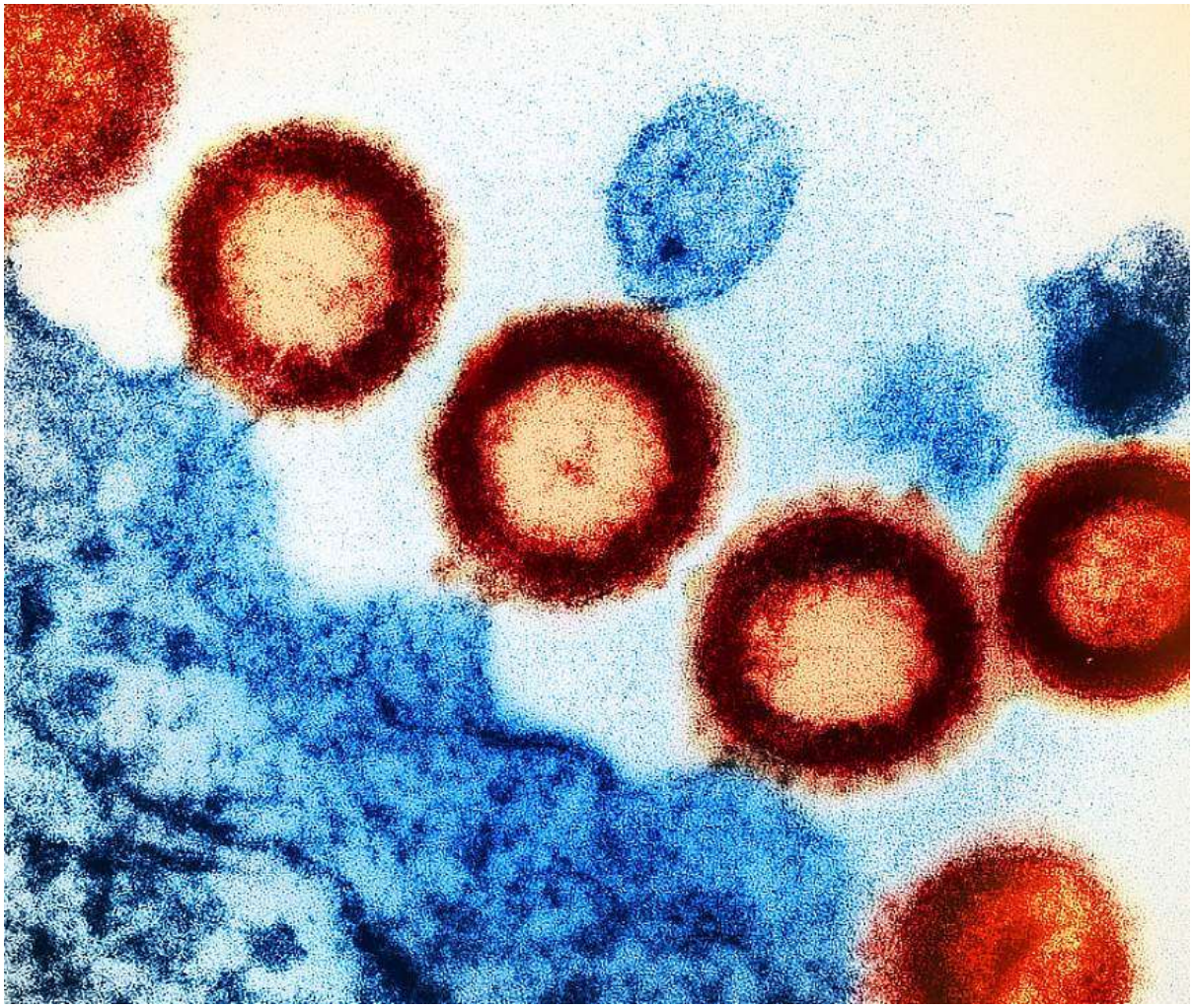
National Institutes of Health
Turning Discovery Into Health

Early HIV diagnosis and treatment important for better long-term health outcomes



Transmission electron micrograph of HIV-1 virus particles (red) replicating from the plasma membrane of an infected H9 T cell (blue). *NIAID*

What

Starting antiretroviral treatment (ART) early in the course of HIV infection when the immune system is stronger results in better long-term health outcomes compared with delaying ART, according to findings presented today at the IDWeek Conference in Washington, D.C.

The findings are based on an extended follow-up of participants in the National Institutes of Health-funded Strategic Timing of Antiretroviral Treatment (START) study. In 2015, START demonstrated (link is external)a 57% reduced risk of AIDS and serious non-AIDS health outcomes among participants who began ART when their CD4+ T-cell counts—a key indicator of immune system health—were greater than 500 cells per cubic millimeter (mm^3) compared with those who did not begin ART until either their CD4+ counts fell below 350 cells/mm^3 or they developed AIDS. Following the 2015 report of these findings, the participants in the deferred treatment arm were advised to begin ART.

Approximately, 1.2 million people in the United States are living with HIV, and roughly 13% do not know they are infected, according to the Centers for Disease Control and Prevention. When HIV diagnosis and treatment are delayed, HIV continues to replicate. This can negatively impact the infected individual's health and increase the risk of transmitting the virus to others.

The international START study proved the benefit of early ART initiation, but longer-term follow-up of 4,446 participants was undertaken to determine whether the health benefits of early ART compared with deferred ART increased, remained constant, or declined after the participants in the deferred arm were advised to begin ART. The primary study endpoints included the number of participants who developed AIDS; those who developed serious non-AIDS health conditions, such as major cardiovascular disease, kidney failure, liver disease and cancer; and those who died.

For participants who began ART before the end of 2015, the median CD4+ cell count at the time of ART initiation was 648 cells/mm^3 for the immediate arm and 460 cells/mm^3 for the deferred arm. The analysis presented today compared the primary study endpoints before the end of 2015, with those in the extended follow-up period, from Jan. 1, 2016, to Dec. 31, 2021. In the latter period, most deferred-arm participants were taking ART. During the second period, people initiating ART in the deferred group had rapid and sustained declines in HIV viral load (less than or equal to 200 copies/mL); however, CD4+ cell counts remained, on average, 155 cells lower compared with that of individuals in the immediate ART group. While the risk of serious health outcomes was substantially diminished soon after ART was initiated in the deferred treatment group, some excess risk remained compared with the immediate treatment group. The deferred ART group continued to have a somewhat greater risk (21%) of serious health consequences or death in comparison to the immediate treatment group. Twenty-seven cases of AIDS occurred in the five-year follow-up period in the deferred treatment group compared with 15 cases in the early treatment group. Similarly, 88 cases of serious non-AIDS health issues occurred in the deferred treatment arm compared with 76 cases in the immediate treatment arm. Lastly, there were 57 deaths in the deferred treatment group compared to 47 in the immediate treatment arm.

These findings confirm that ART significantly improves the health of an individual with HIV and reduce the person's risk of developing AIDS and serious health issues, and that early diagnosis and treatment are key to maximizing these benefits and reducing risk, according to the presenters.

The START study and its extended follow up was conducted by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), funded in part by the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH. It was led by principal investigator James D. Neaton, Ph.D., of the University of Minnesota, Minneapolis, and START study co-chairs Abdel Babiker, Ph.D., of the University College London, and Jens Lundgren, M.D., of the University of Copenhagen.

When

Infectious Disease Society of America's IDWeek in Washington, D.C. Presentation title, "Long term benefits from early antiretroviral therapy initiation in HIV infection: findings from the extended follow up of the START trial." Saturday, Oct. 22, 2022, at 1:20 p.m. EDT.

Who

Carl Dieffenbach, Ph.D., director of NIAID's Division of AIDS, and Beverly L. Alston-Smith, M.D., chief of the Complications and Co-Infections Research Branch within NIAID's Division of AIDS, are available to comment on this presentation.

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