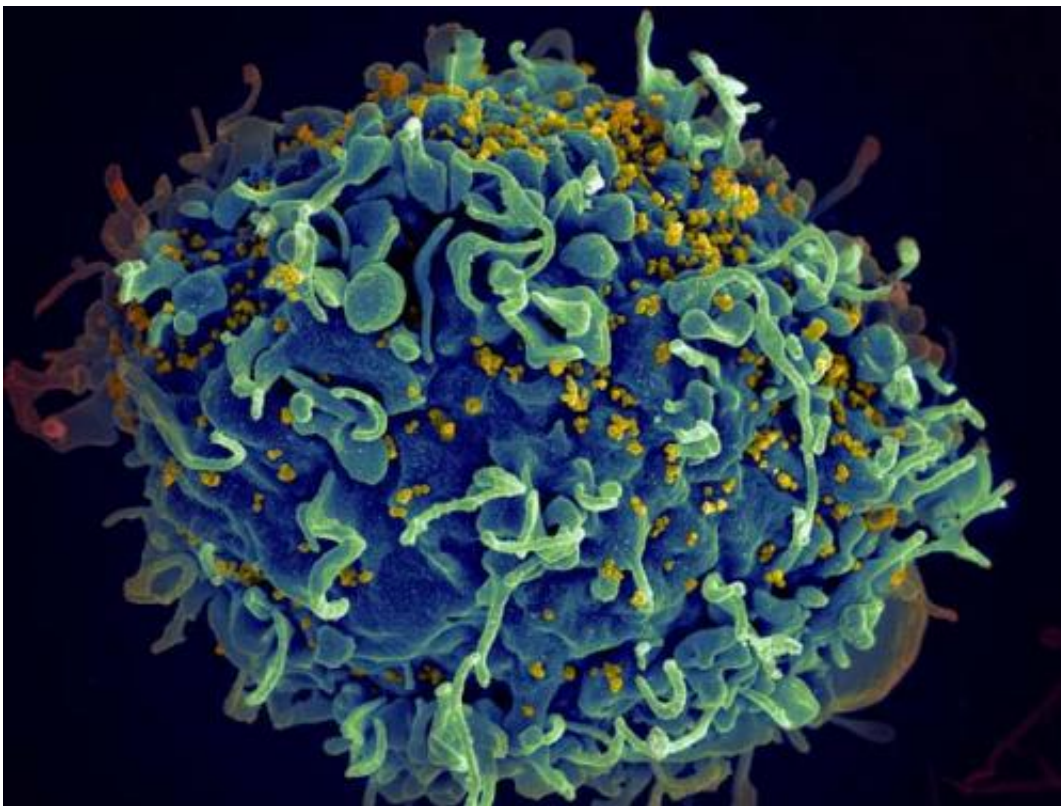


Starting antiretroviral treatment early improves outcomes for HIV-infected individuals

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HIV, the AIDS virus (yellow), infecting a human immune cell. Credit: Seth Pincus, Elizabeth Fischer and Austin Athman, National Institute of Allergy and Infectious Diseases, National Institutes of Health.

A major international randomized clinical trial has found that HIV-

infected individuals have a considerably lower risk of developing AIDS or other serious illnesses if they start taking antiretroviral drugs sooner, when their CD4+ T-cell count—a key measure of immune system health—is higher, instead of waiting until the CD4+ cell count drops to lower levels. Together with data from previous studies showing that antiretroviral treatment reduced the risk of HIV transmission to uninfected sexual partners, these findings support offering treatment to everyone with HIV.

The new finding is from the [Strategic Timing of AntiRetroviral Treatment \(START\) study](#), the first large-scale randomized clinical trial to establish that earlier antiretroviral [treatment](#) benefits all HIV-infected individuals. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, provided primary funding for the START trial. Though the study was expected to conclude at the end of 2016, an interim review of the study data by an independent data and safety monitoring board (DSMB) recommended that results be released early.

"We now have clear-cut proof that it is of significantly greater health benefit to an HIV-infected person to start antiretroviral therapy sooner rather than later," said NIAID Director Anthony S. Fauci, M.D.

"Moreover, early therapy conveys a double benefit, not only improving the health of individuals but at the same time, by lowering their viral load, reducing the risk they will transmit HIV to others. These findings have global implications for the treatment of HIV."

"This is an important milestone in HIV research," said Jens Lundgren, M.D., of the University of Copenhagen and one of the co-chairs of the START study. "We now have strong evidence that early treatment is beneficial to the HIV-positive person. These results support treating everyone irrespective of CD4+ T-cell count."

The START study, which opened widely in March 2011, was conducted by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT) at 215 sites in 35 countries. The trial enrolled 4,685 HIV-infected men and women ages 18 and older, with a median age of 36. Participants had never taken antiretroviral therapy, and were enrolled with CD4+ [cell counts](#) in the normal range—above 500 cells per cubic millimeter (cells/mm³). Approximately half of the study participants were randomized to initiate [antiretroviral treatment](#) immediately (early treatment), and the other half were randomized to defer treatment until their CD4+ cell count declined to 350 cells/mm³. On average, participants in the study were followed for three years.

The study measured a combination of outcomes that included serious AIDS events (such as tuberculosis and AIDS-related cancer), serious non-AIDS events (major cardiovascular, renal and liver disease and cancer), and death. Based on data from March 2015, the DSMB found 41 instances of AIDS, serious non-AIDS events or death among those enrolled in the study's early treatment group compared to 86 events in the deferred treatment group. The DSMB's interim analysis found risk of developing serious illness or death was reduced by 53 percent among those in the early treatment group, compared to those in the deferred group.

Rates of serious AIDS-related events and serious non-AIDS-related events were both lower in the early treatment group than the deferred treatment group. The risk reduction was more pronounced for the AIDS-related events. Findings were consistent across geographic regions, and the benefits of early treatment were similar for participants from low- and middle-income countries and participants from high-income countries.

"The study was rigorous and the results are clear," said INSIGHT principal investigator James D. Neaton, Ph.D., a professor of

biostatistics at the University of Minnesota, Minneapolis. "The definitive findings from a randomized trial like START are likely to influence how care is delivered to millions of HIV-positive individuals around the world." The University of Minnesota served as the trial's regulatory sponsor and statistical and data management center.

Prior to the START trial, there was no randomized controlled trial evidence to guide initiating treatment for individuals with higher CD4+ cell counts. Previous evidence to support early treatment among HIV-positive people with CD4+ cell counts above 350 was limited to data from non-randomized trials or observational cohort studies, and on expert opinion.

START is the first large-scale randomized clinical trial to offer concrete scientific evidence to support the current [U.S. HIV treatment guidelines](#), which recommend that all asymptomatic HIV-infected individuals take antiretrovirals, regardless of CD4+ cell count. Current World Health Organization HIV treatment guidelines recommend that HIV-infected individuals begin antiretroviral therapy when CD4+ cell counts fall to 500 cells/mm³ or less.

In light of the DSMB findings, study investigators are informing all participants of the interim results. Participants will be offered treatment if they are not already on [antiretroviral therapy](#), and they will continue to be followed through 2016.

Provided by NIH/National Institute of Allergy and Infectious Diseases

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