Proof That Early Treatment Is Ideal

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Researchers have finally produced gold-standard scientific evidence that starting antiretroviral (ARV) treatment soon after an HIV diagnosis reduces the risk of sickness and death when compared with putting off treatment until HIV disease progresses. Although U.S. treatment guidelines have recommended universal treatment regardless of CD4 count since 2012, this policy was backed by research that provided a lower standard of proof than this new, definitive research.

The START study was a randomized controlled trial including 4,685 HIV-positive women and men who had never been treated for the virus and who began the trial with CD4 counts above 500. The participants, who lived in 35 countries, were randomly assigned to begin treatment immediately or to wait until one of the following occurred: their CD4s dropped to 350 or below; they developed AIDS or other serious illnesses; or they met other qualifications for starting treatment according to local guidelines, such as by becoming pregnant.

The participants began the trial a median of one year after being diagnosed with HIV and with a median CD4 count of 650. The members of the immediate treatment group went on ARVs at that point. Almost half of the deferred group eventually started treatment, with an average of about 400 CD4s. The main reason those in the delayed arm began ARVs was because they fell below the 350 threshold. Aside from that, some developed AIDS-defining illnesses, others became pregnant, and some asked to start treatment when their viral loads rose or their CD4 levels dropped considerably, although not to 350. Participants were allowed to start treatment at any time they chose and for any reason.

The study began enrollment in 2011 and was intended to run under its established protocol through the end of 2016. However, in the spring of 2015 an independent safety monitoring board determined that early treatment was already clearly very beneficial, reducing by 53 percent the risk of AIDS diagnoses, serious non-AIDS illnesses—including a major cardiovascular problem, kidney or liver disease, and cancer—and death. (During an average of about three years of follow-up there were 41 instances of these outcomes in the early treatment group and 86 in the delayed group—low numbers in each category.) So all of those who were in the deferred treatment group were then offered ARVs immediately.

During a May 27 teleconference, Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases, remarked that the trial results bring into better sync the dual use of ARVs

among people living with HIV: as prevention (successful treatment vastly reduces the risk of passing on the virus), and as life-saving treatment.

Calling the START results “more scientific evidence to back what we’ve been saying for a long time now,” Fauci said the findings are “another reason why we should be more aggressive seeking out voluntary testing, linking to care and putting people on treatment.”
