Solid Evidence Backing Early HIV Treatment Finally Arrives

May 27, 2015 By Benjamin Ryan

For the first time, a major clinical trial has found that starting antiretroviral treatment soon after HIV diagnosis reduces the risk of sickness and death when compared with delaying treatment until HIV disease progresses. Until now, only substandard research supported the U.S. treatment guidelines' recommendation for immediate HIV treatment regardless of CD4 count. According to the National Institute of Allergy and Infectious Diseases (NIAID), the primary backer of the study, the findings support offering ARVs to everyone living with HIV.

"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," NIAID director Anthony S. Fauci, MD, said in a press release. "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."

The randomized controlled Strategic Timing of AntiRetroviral Treatment (START) trial included 4,685 treatment-naive HIV-positive adults with a CD4 count above 500 and no symptoms of the virus at the outset. They were randomly assigned, about half and half, to begin treatment immediately or to wait until their CD4s dropped to 350 or below, or until they developed AIDS or other serious illnesses.

START, which was conducted by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), began enrollment in 2011 and operated at 215 sites in 35 countries. The trial was intended to run under its initial protocol until the end of 2016. But the study's independent data safety monitoring board conducted an interim analysis of the study based on March 2015 data and found that evidence supporting the benefits of early treatment was already very strong. Consequently, the board recommended that everyone in the trial be informed of the results and offered immediate treatment. The participants will still be monitored through 2016.

The global HIV community has awaited the results with bated breath, because START is the first randomized controlled trial (considered the gold standard of medical research) to address the question of whether it is preferable to begin ARV treatment at high CD4 counts. Until now, randomized controlled trial data only supported starting ARVs after CD4s drop below 350.

Twenty-seven percent of the study participants were women. Half were men who have sex with

men (MSM). The median age was 36.

The participants began the trial with an average CD4 count of 650 to 700, so those in the immediate treatment arm began ARVs within that CD4 range. The deferred group started treatment with an average of about 400 CD4s.

After an average three years of follow-up, those in the immediate treatment arm experienced 41 instances of AIDS diagnoses, serious non-AIDS illnesses (including a major cardiovascular problem, kidney and liver disease, and cancer) or death, compared with 86 instances in the deferred group. Thus, starting treatment immediately reduced the risk of such outcomes by 53 percent. The risk reduction was even greater for AIDS diagnoses.

The benefits of early ARV treatment were consistent across regions and similar between those in low- and middle-income nations when compared to those in high-income nations.

“The study was rigorous and the results are clear,” INSIGHT principal investigator James D. Neaton, PhD, a professor of biostatistics at the University of Minnesota, Minneapolis, said in the same press release. “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.

Currently, the World Health Organization has recommended starting HIV treatment once CD4s drop below 500. U.S. Department of Health and Human Services (HHS) treatment guidelines recommend starting HIV treatment immediately after diagnosis, regardless of CD4 count. However, the U.S. recommendation for early treatment is only based on “expert opinion.” The results from the START trial are likely to change this.

To read the press release on the START trial, click here.

To read a recent POZ feature about experts who, without the benefit of the START results, debated when it is best to start HIV treatment, click here.

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http://beta.docker.poz.com/article/START-early-treatment-27290-2863