

NIH Study Examines Best Time for Healthy HIV-infected People to Begin Antiretrovirals

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A major new clinical trial seeks to determine whether HIV-infected asymptomatic individuals have less risk of developing AIDS or other serious illness if they begin taking antiretroviral (ARV) medicines sooner rather than later based on their level of CD4+ T-cells (a key measure of immune system health). The study is co-funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Currently, data from randomized clinical trials exist to support starting ARVs when CD4 counts fall below 350 cells per cubic millimeter (mm³). However, trials have not been conducted to guide decisions to support starting treatment when CD4 counts are higher than 350. As a result, guidelines differ regarding if and when to begin ARV treatment in healthy HIV+ individuals with CD4 counts above 350. Current U.S. guidelines recommend starting ARVs when the CD4 count drops below 500. The World Health Organization recommends starting treatment when CD4s fall below 350.

This new study known as the Strategic Timing of Antiretroviral Treatment (START) is a randomized clinical trial designed to provide definitive evidence of the risks and benefits of early treatment with ARVs to more clearly define the optimal time to begin taking medication. The study seeks to determine if immediate ARV therapy among HIV+ individuals with CD4 counts above 500 is better than waiting until CD4 counts fall below 350 in terms of the potential benefits and risks (such as developing AIDS and other serious illnesses including cardiovascular disease, cancer, kidney failure and liver disease or death).

“Some evidence suggests that patients with HIV remain healthier when they begin treatment at higher CD4 counts. However, there are also concerns about the health complications and side effects associated with lifelong ARV use and the possibility that the virus may become resistant to the medications,” says NIAID Director Anthony S Fauci, M.D. “The START trial will provide a more clear-cut answer as to the best time for HIV patients to begin treatment, taking into account both the risks and benefits associated with starting treatment sooner versus later.

START will be conducted in 30 countries. It will enroll 4,000 HIV+ men and women 18 years and older who have CD4 counts above 500 who have never taken ARVs. Once entered into the study, half of the participants will be randomly assigned to receive immediate therapy. The other half of the study group will not receive ARV therapy until their CD4 counts fall below 350 or when an AIDS-related event occurs. Participants will be followed for up to five years. Once enrolled, they will be seen by study staff at one month, four months and then every four months thereafter. At each visit, participants will provide a medical update and undergo a brief medical exam and CD4 counts and viral load (the amount of HIV in the blood) will be recorded.

Dr. Barbara Wade in Pensacola at the Centers for the Prevention and Treatment of Infections and HIV Care Center, Inc. is a study site for the START clinical trial. Eligible patients who would like to participate will receive their medications at no cost. You do not have to be a patient of Dr. Wade or leave your current provider in order to participate in the study. For more information, please call (850)476-3131 and ask to speak with Ann Brown, RN - the START study coordinator.