

Study explores prevention of heart disease in HIV-infected people

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The National Institutes of Health has launched a clinical trial to assess the effects of aspirin and cholesterol-lowering drugs, or statins, on preventing cardiovascular disease in people with long-term HIV infections. This group, which includes people on antiretroviral therapy (ART) as well as "elite controllers" who can limit the virus without ART, have a higher risk of developing heart disease and stroke compared to the general population. The study is funded by NIH's National Institute of Allergy and Infectious Diseases (NIAID).

"With the remarkable success of <u>antiretroviral therapy</u>, people living with HIV have a near-normal life expectancy," said NIAID Director Anthony S. Fauci, M.D. "However, as this population ages, noninfectious complications such as <u>cardiovascular disease</u> begin to arise. We need to study the effects on the immune system of drugs normally prescribed for these conditions to ensure that they are beneficial for HIVinfected individuals."

Researchers have long speculated that the enhanced risk of <u>heart disease</u> and stroke in people with long-term controlled HIV infections is associated with drug toxicity, immune defects and <u>chronic inflammation</u>. This study will specifically examine the role of chronic inflammation and allow researchers to observe how drug-related changes influence the levels of virus.

"Elite controllers and people on ART have elevated levels of clotting factors and blood markers that indicate inflammation and an active



immune response," said Irini Sereti, M.D., chief of the HIV Pathogenesis Unit in the NIAID Laboratory of Immunoregulation, which leads the clinical trial. "Over time, these factors likely contribute to an enhanced risk of cardiovascular disease, so if we can lower the levels of these factors with aspirin or statins, then maybe we can lower the risk of disease, too."

The study, which is currently recruiting, will enroll <u>elite controllers</u> and people on ART who have not taken aspirin or statins during the past six months. The participants will be monitored for three months to establish baseline levels of clotting and inflammatory agents in their blood. Afterward, participants will be assigned randomly to either a regimen of aspirin or atorvastatin for nine months. The researchers will monitor clotting and inflammatory markers from blood samples and use MRI scans to measure the thickness of blood vessels in the neck.

Provided by NIH/National Institute of Allergy and Infectious Diseases

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