

NIH launches largest clinical trial focused on HIV-related cardiovascular disease

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Researchers have begun enrolling participants in a multicenter international clinical trial to test whether statin administration can reduce the risk for major adverse cardiovascular events, such as heart attacks, strokes, and heart disease, in people with HIV infection. The trial is supported by the National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI) and National Institute of Allergy and Infectious Diseases (NIAID).

Known as the Randomized Trial to Prevent Vascular Events in HIV, or REPRIEVE, the [randomized clinical trial](#) is the largest to date focused on HIV-related cardiovascular disease. Researchers hypothesize that statins should reduce plaque development and improve [cardiovascular outcomes](#) in patients with HIV. The ultimate objective of the trial is to inform the best clinical approach to preventing cardiovascular disease in people infected with HIV.

Research suggests that people with HIV are up to twice as likely as people without HIV infection to have heart attacks and other forms of cardiovascular disease, even after controlling for traditional risk factors such as elevated cholesterol, high blood pressure, and smoking. However, there are no evidence-based therapies to lower the increased cardiovascular disease risk in people who have HIV. Statins are a class of drugs that have been previously demonstrated to be safe and effective in lowering [cholesterol levels](#) as well as the risk of major adverse [cardiovascular events](#) in non-HIV populations.

Because HIV-infected men and women are now living much longer lives due to successful [antiretroviral therapy](#), it is increasingly important to help them prevent cardiovascular disease to improve both their quality of life and their longevity. Thirty years ago, a 20-year-old diagnosed with HIV had only months to live, but today, a newly diagnosed 20-year-old who promptly starts antiretroviral therapy can expect to live another 50 years.

"I am delighted that NHLBI and NIAID have joined forces to foster cross-disciplinary collaboration between cardiovascular and HIV researchers so that we can improve the lives of millions of people worldwide living with HIV and reduce the burden of cardiovascular disease," said NHLBI Director Dr. Gary H. Gibbons, M.D.

A number of factors combine to put people with HIV at increased risk for cardiovascular disease. First, HIV causes inflammation that results in activated immune cells, both of which contribute to plaque buildup in the arteries (also known as atherosclerosis). This in turn leads to cardiovascular disease. Second, a well-documented consequence of antiretroviral therapy is higher cholesterol levels, which may contribute to [cardiovascular disease risk](#). And third, the rates of some conventional risk factors for cardiovascular disease, such as smoking, are also higher in the HIV-infected population.

"Research suggests that cholesterol-lowering statins may inhibit immune cell activation and inflammation and shrink arterial plaque," said NIAID Director Anthony S. Fauci, M.D. "Therefore, these medications provide an intriguing possibility for improving cardiovascular outcomes in people with HIV."

Investigators from Massachusetts General Hospital/Harvard Medical School (Steven Grinspoon, M.D. and Udo Hoffmann, M.D., M.P.H.), Harvard School of Public Health (Heather Ribaldo, M.D.) and Duke

University (Pamela Douglas, M.D.) will conduct the trial in collaboration with the NIH-funded AIDS Clinical Trials Group (ACTG). Roughly 100 sites in Canada, Puerto Rico, Thailand and the United States will participate. Investigators plan to randomize 6,500 HIV-infected participants between the ages of 40 to 75 years who would not meet current national guidelines for statin therapy to either a daily dose of pitavastatin or a placebo while continuing with antiretroviral therapy. Pitavastatin was selected for this trial because, unlike most other statins, only minimal interactions occur between pitavastatin and drugs for treating HIV.

Investigators will follow the participants for up to six years, assessing them for the development of major adverse cardiovascular events, such as heart attacks and strokes. The researchers will also evaluate the safety of statin therapy; the effects of statins on cholesterol levels, immunologic parameters, and serious non-cardiovascular disease events, such as new-onset diabetes; and gender differences in the effects of statins on people with HIV. Additionally, investigators will conduct a sub-study involving 800 participants to examine the effects of pitavastatin on coronary artery disease and inflammatory biomarkers in HIV-infected individuals.

Although REPRIEVE is focused on people living with HIV, the study will provide general insights on the role of inflammation in the development of atherosclerosis and thus may provide knowledge that may benefit all patients with [cardiovascular disease](#).

REPRIEVE is primarily funded by the NHLBI. The study will be conducted in partnership with NIAID, which supports the ACTG. Kowa Pharmaceuticals America, Inc., is donating the study drug and placebo and providing a monetary donation.

The NHLBI is supporting this study through U01 grants HL123336,

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More information: www.niaid.nih.gov/about/organizational/retrieveTrial.aspx

Provided by NIH/National Institute of Allergy and Infectious Diseases

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