Statin Reduces Cardiovascular Risk for People With HIV

Large trial finds that pitavastatin lowered the risk for major cardiovascular events by 35%.

April 12, 2023 By Liz Highleyman

The REPRIEVE study, a large global trial testing a statin for HIV-positive people at low to moderate risk for cardiovascular disease, was halted ahead of schedule after interim results showed that the medication significantly reduced the risk for heart attacks, strokes and other major cardiovascular events, the National Institutes of Health (NIH) announced this week.

"The REPRIEVE study reflects the evolution of HIV science and progress from focusing mostly on approaches to treat and control the virus to finding ways to improve the overall health of people living with HIV," Hugh Auchincloss, MD, acting director of the National Institute of Allergy and Infectious Diseases, said in an NIH press release. "These new data suggest that a common cholesterol-lowering medicine could substantially improve cardiovascular outcomes in people with HIV."

A large body of research has shown that people living with HIV are at greater risk for cardiovascular disease (CVD). Reasons for this disparity may include chronic inflammation, adverse effects of certain antiretroviral drugs and higher rates of traditional risk factors, such as smoking. Elevated blood fat levels are associated with cardiovascular disease. Statins, which lower cholesterol, have been shown to reduce the risk for heart attacks, other cardiovascular events and death in the general population, but their benefits for people with HIV were unknown.

REPRIEVE, the Randomized Trial to Prevent Vascular Events in HIV (NCT02344290), sponsored by the NIH and conducted by the AIDS Clinical Trials Group, began enrollment in 2015. The largest randomized HIV trial to date, it was conducted in 12 countries in North and South America, Europe, Africa and Asia. The study enrolled nearly 7,800 people living with HIV ages 40 to 75 who were on stable antiretroviral therapy and had a CD4 T-cell count above 100. Nearly one third were women.

The study participants had no prior history of atherosclerotic cardiovascular disease and had comorbidities and laboratory values (including cholesterol and triglyceride levels) consistent with low to moderate CVD risk—a population that normally would not be advised to take statins. The U.S. Preventive Service Task Force recommends statins for HIV-negative adults with one or more CVD risk factors and a 10% or greater 10-year risk for cardiovascular events. But research shows that people with HIV are more likely to develop CVD at younger ages, and traditional risk scores

used for the general population underestimate CVD risk in people with HIV.

REPRIEVE participants were randomly assigned to take a pitavastatin pill (Livalo or generic equivalents) or a placebo pill once daily. They were monitored for major cardiovascular events, including myocardial infarction, stroke, unstable angina (chest pains), peripheral artery disease, revascularization procedures (such as stents or coronary bypass surgery) or CVD-related death. They were also monitored for statin side effects and drug interactions, though pitavastatin is considered safe to use with all antiretroviral regimens.

The trial's independent Data Safety and Monitoring Board (DSMB) met periodically to review interim results. At its most recent meeting, the board recommended that the study should be stopped early because the statin was already showing a clear benefit. Participants who took pitavastatin had a 35% lower risk for major cardiovascular events, making it unethical to keep some participants on the placebo. Side effects were similar to those seen in the general population.

Study participants are being notified of the findings and will continue to be monitored for several months, according to the NIH announcement. Researchers will collect full data across all sites for a final analysis. Results from the DSMB review "are expected to be published in the coming weeks."

In addition to its primary outcome, REPRIEVE and its various sub-studies collected a wealth of valuable information over the course of nearly a decade. The study found that participants often had reduced kidney function and fat around the heart, had high rates of atherosclerosis and inflammation and were more likely than HIV-negative people to have abnormal heart rhythms. It even shed light on COVID-19 among people living with HIV.

"These latest findings represent the culmination of an unprecedented eight-year effort to generate evidence that can help clinicians better support the unique cardiovascular health needs of people living with HIV," said Gary Gibbons, MD, director of the National Heart, Lung, and Blood Institute. "REPRIEVE is important because there are limited existing interventions to help prevent adverse cardiovascular outcomes in this population."

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