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# Effects of Pitavastatin on Coronary Artery Disease and Inflammatory Biomarkers in HIV: Mechanistic Substudy of the **REPRIEVE Randomized Clinical Trial**

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### Background

The risk of heart disease is higher among people with HIV (PWH), including among younger individuals with lower predicted heart disease risk. It is also common for PWH to have plaque (fatty build up) in the blood vessels that supply the heart (coronary arteries). It is not fully understood why heart disease risk is higher among PWH, but researchers believe it could be related to both traditional risk factors, like smoking, and to HIV-related factors, like inflammation (the body's response to infection). It is important to address the higher risk of heart disease in PWH and develop a strategy to treat it.

Participants in this study were enrolled in the Mechanistic Substudy of REPRIEVE. REPRIEVE is a global clinical research trial that showed that treatment with pitavastatin (a cholesterol-lowering medication) reduces heart disease (including heart attack and stroke) in PWH by 35%. U.S. REPRIEVE participants in the Mechanistic Substudy underwent main REPRIEVE trial procedures, as well as CT scans of the blood vessels surrounding the heart and blood tests measuring blood levels of inflammation markers.

# Goals of the Study

To determine the effects of 2 years of pitavastatin on 1) the amount of plaque in the arteries and 2) on blood levels of inflammation markers.

# $\succ$ The participants:

- o 611 REPRIEVE participants
  - 302 randomly assigned to take pitavastatin and 309 to take placebo
  - Average age: 51 years
  - o 98 (16%) were female sex
  - o 220 (36%) were Black or African American

#### $\geq$ The findings:

- Pitavastatin reduced the amount of non-calcified plaque (a type of plaque that is less stable) by 7% compared to placebo. Progression of non-calcified plaque was 33% less likely with pitavastatin compared to placebo.
- Pitavastatin led to reductions in inflammation markers (oxidized LDL and lipoprotein-associated phospholipase A2).

In Summary: Pitavastatin lowered the amount of non-calcified coronary plague and inflammation markers in PWH. These results may help explain why pitavastatin reduced heart disease events among participants in the overall REPRIEVE trial.

### REPRIEVE Trial Website: reprievetrial.org