Case Western Reserve University/University Hospitals Case Medical Center
AIDS Clinical Trials Unit

A5332 Randomized Trial to Prevent Vascular Events in HIV

Provider Summary Sheet for ACTG5332

Brief Summary: The REPRIEVE trial is a multi-center prospective, double-blind, randomized, placebo-controlled phase 4 trial of pitavastatin versus placebo for approximately 72 months. The trial is testing the effect of statin primary preventive therapy on CVD events in HIV-infected persons on ART not meeting 2013 ACC/AHA guideline thresholds for recommended statin initiation.

Primary Clinical Objective: To determine the effects of pitavastatin as a primary prevention strategy for major adverse cardiovascular events (MACE) in HIV.

Treatment Arms: At study entry, subjects will be randomized to one of the following arms:

- ARM A: At Day 0, continue ART (not provided by the study) and initiate pitavastatin 4 mg one tablet once daily taken orally with or without food.
- ARM B: At Day 0, continue ART (not provided by the study) and initiate pitavastatin placebo one tablet once daily taken orally with or without food.

Key Inclusion Criteria:

- HIV-1 infection
- Combination antiretroviral therapy (ART) for at least 6 months prior to study entry
- CD4+ cell count >100 cells/mm^3 obtained within 180 days prior to study entry
- Laboratory values within 90 days prior to study entry as per protocol
- For persons with known chronic active hepatitis B or C, calculated FIB-4 score must be <3.25
- Not pregnant, not planning to get pregnant, not planning to impregnate
- Men and women age ≥ 40 and ≤ 75 years of age

Key Exclusion Criteria:

- Clinical ASCVD, as defined by 2013 ACC/AHA guidelines acute coronary syndromes; stable or unstable angina; coronary or other arterial revascularization; stroke; TIA; or peripheral arterial disease presumed to be of atherosclerotic origin
- 10-year ASCVD risk score estimated by Pooled Cohort Equations ≥10%
- Cancer free for <3 years prior to study entry
- Known cirrhosis
- History of myositis or myopathy with active disease in the 180 days prior to study entry.
- Known untreated symptomatic thyroid disease.
- History of allergy or severe adverse reaction to statins
- Use of drugs specified by protocol 180 days prior to study entry
- Known active or recent (not fully resolved within 30 days prior to study entry) systemic bacterial, fungal, parasitic, or viral infections (except HIV, HBV, HPV, or HCV).

Study Duration: Up to 72 months.

Number of Participants: Up to 6500 people will enroll in this study.

For more information on this trial, please contact
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