



**Randomized Trial to Prevent Vascular Events in HIV
Participant Summary Sheet for ACTG A5332**

Brief Description:

In this study, people living with HIV between the ages of 40 and 75 will be randomly selected (like flipping a coin) to take the medicine pitavastatin OR a placebo (a pill with no active medicine). This study will help answer the question whether pitavastatin can help prevent cardiovascular disease, such as heart disease, in people living with HIV who are taking anti-HIV medicines (ART). The study lasts approximately 6 years. Participants will not know if they are taking pitavastatin or placebo until the trial is over, unless they need to find out sooner for health purposes. The REPRIEVE trial will enroll 6500 people at many clinical trial units in several countries.

Purpose of this Study:

HIV can cause inflammation (irritation) inside the body that cannot be felt but is thought to be a cause of the higher risk that people living with HIV can have for certain diseases and conditions. For example, inflammation may contribute to heart disease which has become one of the leading causes of death in people with HIV. Anti-HIV medicines do lower inflammation levels, but these levels can remain higher when compared to people who do not have HIV.

Statins, like pitavastatin, while used to lower the people's cholesterol levels, have also been shown to lower inflammation levels. **The main purpose of this clinical trial is to see if pitavastatin can prevent heart disease in people living with HIV.**

Requirements to Enter Study: Below are some of the requirements to join the trial. A Clinical Trials Unit staff member can explain other requirements to join the study.

- People living with HIV between the ages of 40 and 75.
- On antiretroviral therapy (ART) for at least 6 months prior to study entry.
- CD4+ cell count >100.
- Must not be pregnant and must agree not to participate in the conception process.
- No history of cardiovascular disease (history of heart attack or stroke, etc.).
- No history of cancer in the last 3 years.
- Not currently using a statin drug.

Treatment: Participants will be selected to take either:

- Pitavastatin 4 mg one pill daily **or**
- Placebo pitavastatin one pill daily.

Duration of Study: Participants will be in this study for up to 6 years. They will need to be seen in clinic for a screening visit, an entry visit, one month later, and then every 4 months.

Compensation is provided.

**For more information about this and other clinical trials being offered at the
Case Western Reserve/University Hospitals AIDS Clinical Trials Unit
call us on our confidential line at 216-844-4444 or email us confidentially at info@case.edu
www.clevelandhiv.org**