ACTG Study A5336 Participant Summary Sheet

A Randomized, Pilot Study of Ruxolitinib in Antiretroviral-Treated HIV-Infected Adults

Brief Description: Antiretroviral therapy (ART) reduces the ability of HIV-1 to produce more copies of itself and brings the amount of HIV-1 in the blood to an undetectable level. However, ART only works on HIV-1 that can be reached in the body and is actively producing more copies of itself. Despite successful treatment with ART, latent reservoirs (infected cells that are not actively producing HIV-1) remain present in the body and may contribute to ongoing immune system activation and inflammation in the body. For individuals with HIV-1, there are many other sources of this inflammation as well. This inflammation can reduce the body's immune response to ART medications and can lead to increased damage to organs (such as the heart and liver).

Ruxolitinib is an FDA-approved medication to treat myelofibrosis, a disorder not related to HIV-1 infection in which bone marrow is replaced by scar (fibrosis) tissue. Many of the cytokines (regulators of the body's reaction to infection, immune response, and inflammation) affected by myelofibrosis are also affected by HIV-1. Because ruxolitinib reduce these cytokines in people with meylofibrosis, it is proposed that it may also reduce inflammation in the bodies of people living with HIV-1 in whom the virus is suppressed by ART. Laboratory experiments have also shown that ruxolitinib may reduce the ability of HIV-1 to produce more copies of itself.

Purpose of this Study: We are doing this study to learn about the safety and tolerability of the use of ruxolitinib in people with HIV-1 infection who have an undetectable HIV-1 RNA viral load. Additionally we want to learn whether ruxolitinib will decrease inflammation and immune activation in the body; whether ruxolitinib will affect the level of HIV in your blood; and how ruxolitinib interacts with ART in the blood.

Requirements to Enter Study:

- Have HIV-1 infection and be at least 18 years old and less than 75
- Be on continuous HIV-1 treatment for the last 2 years with undetectable HIV-1 viral load, and no plans to change the medications for the 12 weeks of the study
- CD4+ T cell (immune cell) blood count 350 or higher
- No other medical conditions or taking any medications that would be contraindicated for individuals taking the study medication

Treatment: A total of 60 individuals will participate in the study. Participants will be randomly assigned to either A) receive 5 weeks of treatment with ruxolitinib as a pill to be taken orally twice a day (40 individuals) or B) No study treatment (20 individuals).

Duration of Study: All individuals will participate in the study for up to 12 weeks.

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