AIDS 400: An open-label pilot study of HIV reservoir reduction with interleukin-2 (STARR)

Participant Summary Sheet

Background: Anti-HIV medicines stop HIV from reproducing and often can bring a person's viral load (the amount of virus in their blood) to a level below detection. However, if a person living with HIV stops taking their anti-HIV medicines, the virus almost always comes back. This is because there are certain resting or latent cells that have HIV DNA hidden inside of them. Anti-HIV medicines do not have an effect on the HIV particles inside cells in a resting or latent state. If these cells "wake up" in the presence of anti-HIV medicine, the medicines will stop them from making new viruses. But if these cells "wake up" and there are no anti-HIV medicines, the virus levels will come back, often quite quickly. These resting or latent cells are collectively called the HIV latent reservoir.

In this study, people living with HIV will take doses of a form of interleukin-2 (IL-2), a naturally occurring substance used by the immune system to increase its ability to fight against organisms such as bacteria or viruses. There have been large clinical trials of IL-2 to increase CD4 T-cell numbers in HIV-infected persons. While participants receiving IL-2 in those trials did achieve higher CD4 T-cell numbers, these increases did not result in clinical benefit. One smaller study, however, did seem to show that the addition of IL-2 to anti-HIV medicines caused a decrease in the HIV latent reservoir, a potentially useful result in the long term goal of developing a sterilizing or functional cure of HIV.

Purpose of this Study: The primary purpose of this study is to compare the size of the participants' HIV latent reservoirs before and after receiving 8 cycles of IL-2. In order to measure the size of the HIV reservoir, all participants will undergo a leukapheresis procedure prior to taking IL-2. These results will be compared with results from another leukapheresis procedure after the participant completes theIL-2 cycles.

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

- People living with HIV between the ages of 18 and 65.
- On same antiretroviral therapy (ART) regimen for at least 1 year and agrees to remain on same regimen for duration of study, unless otherwise medically indicated.
- CD4+ cell count 350 or more.
- HIV viral load below the levels of detection for at least one year (viral blip of 500 allowed).
- Women with childbearing potential may not enroll in this study.
- No acute or chronic hepatitis B or C. People who have successfully been treated for hepatitis C are eligible to enroll in this study.

Treatment: Each participant will go through 8 study periods. Each period is 8 weeks long. Participants will take, through subcutaneous injection, a cycle of IL-2, consisting of 8 doses of IL-2 in 4 days (2 doses per day) in each period.

Duration of Study: Participants will be in this study for approximately 1 and ½ years. This includes the initial screening visit to determine eligibility to join the trial.

Compensation: Provided.

For more information about this and other clinical trials being offered at the
Case Western Reserve University / 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