ACTG A5386
Participant Information Sheet
Full Title: "A Phase 1 Clinical Trial of the Safety, Tolerability, and Efficacy of IL-15 Superagonist (N-803) with and without Combination Broadly Neutralizing Antibodies to Induce HIV-1 Control During Analytic Treatment Interruption"

Brief Description: Researchers are looking for ways to get rid of HIV that rests hidden in areas of the body where current anti-HIV medicines can't reach. This trial looks at the safety and tolerability of three new experimental drugs and whether these drugs can help a person control HIV without anti-HIV medicines.

Study Products:

IL-15 superagonist (N-803), a new experimental drug, appears to reactivate HIV that is "asleep" and is also thought to increase the body's natural immune response to HIV. N-803 is given by a small needle under the skin, similar to a shot of insulin.

Broadly neutralizing antibodies (bNAbs), such as 10-1074 and VRC07-523LS, have been shown to control growth of HIV in the blood and to increase the body's immune response to HIV. The hope is that these antibodies could attack the cells of the body that contain the reactivated HIV. These antibodies are given through an infusion, also known as an "IV."

Clinical Trials Terms and Procedures:

Leukapheresis is a procedure in which blood is collected from a vein in one arm, processed through a machine, and returned to through a vein in the opposite arm. The length of the procedures can vary from 1 to 4 hours.

An Analytic Treatment Interruption (ATI) is where clinical trial participants temporarily stop taking their anti-HIV medicines in order to see if the experimental treatment has been effective in making the participant's body more capable of controlling the HIV without the medicines. During the ATI, the HIV and a participant's health are closely monitored. If a participant meets pre-determined criteria or the ATI period ends, they restart their anti-HIV medicines. Of course, a participant always has the right to choose to restart their anti-HIV medicines earlier. This should be done under a physician's supervision. It is important for participants to understand that during an ATI, their HIV viral load may become detectable and pose a risk of HIV transmission to their sexual partners. So, they should take the appropriate precautions.

How the Study Works: People who enroll in the study will be randomly, like the flip of a coin, placed into one of two groups or arms. People will be told to which arm they have been assigned. The only difference between the two arms is that people in Arm 1 will only receive N-803, while people in Arm 2 will receive N-803 and the two antibodies, 10-1074 and VRC07-523LS. There are no placebos in this clinical trial.

Part 1: study products for 52 wks	Part 2: ATI for 24 wks max	Part 3: restarting anti-HIV meds for 24 wks

Part 1, Receipt of Study Products. Part 1 of the clinical trial will last about one year (52 weeks). During that time everyone will receive 8 doses of N-803. People in Group 2 will also receive one dose of VRC07-523LS and two doses of 10-1074 during Part 1. During Part 1, everyone will undergo two leukapheresis procedures – one at the beginning of the study and one at week 32.

Including the screening visit, people in Arm 1 will have 20 scheduled visits during Part 1. People in Arm 2 have one additional scheduled visit, for a total of 21.

Part 2, analytic treatment interruption. Part 2 of the clinical trial will last a maximum of six months (24 weeks), but usually will be much briefer – approximately 2 months. During Part 2, participants will stop taking their anti-HIV medicines. During the first 12 weeks of Part 2 (if it lasts that long), participants will come to the clinic once a week. Following, week 12, participants will be scheduled to come to the clinic every two weeks. Participants will have at least 19 clinic visits during Part 2 of the trial (if the part 2 analytical treatment interruption last that long).

Part 3, restarting anti-HIV medicines. At the end of the 24 weeks in Part 2 or if a participant meets any of the restart criteria, they will move to Part 3 of the clinical trial, restarting their anti-HIV medicines. This must be done under supervision of a physician. Part 3 lasts for 24 weeks. There are 4 scheduled visits during Part 3 of the clinical trial.

Part 1: study products for 52 wks	Part 2: ATI for 24 wks max	Part 3: restarting anti-HIV meds for 24 wks

Major requirements for entering the study:

- Living with HIV, 18–70 years old.
- Have a low or undetectable viral load for at least 2 years.
- Agree to use contraception/birth control methods.
- Be willing to temporarily stop taking anti-HIV medicines.

Events or conditions that would prevent participation:

- Recent serious illness or condition requiring hospitalization.
- Breastfeeding or pregnant.
- Active Hepatitis B or C infection or history of AIDS-defining conditions.
- Current CD4 cell count less than 500 or ever had a CD4 cell count less than 200.

Talk to your study staff for a complete list of inclusion/exclusion criteria.

Compensation is provided.

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