CWRU/UH AIDS Clinical Trials Research Site
AIDS Clinical Trials Group #5377
Potential Participant Summary

A Phase I, First-in-Human, Ascending Dose Study of SAR441236, a Tri-specific Broadly Neutralizing Antibody, in Participants living with HIV

Background: An antibody is a type of protein that helps the body fight infections. Antibodies are usually made by a person's own immune system in response to a virus or bacteria. But they can also be manufactured or made like a drug and given to people. There are clinical trials going on now for HIV prevention and treatment where people are being given human-made antibodies.

When a person becomes HIV infected, their body will respond by making antibodies to HIV. These antibodies attach to one part of the virus to help the body's immune system to kill or stop the virus from reproducing. Unfortunately, the vast majority of these antibodies do not work well enough to stop HIV from eventually weakening a person's immune system. Fortunately, we have anti-HIV medicines that work to stop the virus from reproducing and can keep a person's viral load undetectable for as long as they take their medicines.

Study product: This trial will be looking at a human-made antibody called SAR441236. Unlike the antibodies created by a person's immune system that attach to HIV at one part, SAR441236 has been made to attach to three parts of the HIV virus at the same time. It is hoped that this will stop the virus from being able to infect more cells. SAR441236 will be given by IV infusion.

First in human/purpose of the trial: This trial is the first time that SAR441236 will be given to people. The primary purpose of the study is to see if SAR441236 is safe and tolerable (side-effects) to give to people, to see if SAR441236 can reduce the amount of HIV in a person's blood and how long does SAR441236 stay in someone's blood over time.

Dose escalation: This study is a dose escalation study, which means that the first people to join the study (Cohort 1) will be in the first given the smallest dose of SAR441236. After safety and tolerability of Cohort 1 has been reviewed and found acceptable, Cohort 2 will enroll and receive a higher dose. There are four cohorts in this study. Cohorts 1-3 receive a single infusion of SAR441236. Cohort 4 will receive up to 4 infusions of SAR441236 over a period of time.

The study will enroll two groups of people living with HIV:
Arm A: People living with HIV who are currently on anti-HIV medicines with an undetectable HIV viral load will receive either SAR441236 or placebo in one of four increasing dosing groups. People in this Arm will continue to take their anti-HIV medicines as prescribed throughout the trial. The trial is not providing the anti-HIV medicines.

Arm B: People living with HIV who have never received anti-HIV medications will receive SAR441236 in one of four increasing dosing groups. Participants will start taking anti-HIV medications by Day 28 of the study. Anti-HIV medicines will not be provided by the study.

Key requirements to enter the study:
People living with HIV, ages 18 to 70 years of age;
No active Hepatitis B or C infection;

For people joining Arm A:
- Taking anti-HIV medications for at least 12 months
- Undetectable" HIV viral load for at least 12 months
- CD4 count greater or equal to 200

For people joining Arm B**:**

Have never taken anti-HIV medications, including PrEP
HIV viral load 5000 to 100,000
CD4 count greater or equal to 350
Willing and able to start anti-HIV medications by day 28 of the study

Treatment:

Arm A**:** Participants who are currently taking anti-HIV medications and have an undetectable viral load will be assigned to one of four Dosing Groups and will be randomly assigned to receive one infusion of SAR441236 or a placebo (saline solution), except for Group 4 which will receive up to 4 infusions. One person will receive placebo for every two people who receive SAR441236.

- Dosing Group 1: 1 mg/kg SAR441236 or placebo
- Dosing Group 2: 3 mg/kg SAR441236 or placebo
- Dosing Group 3: 10 mg/kg SAR441236 or placebo
- Dosing Group 4: 30 mg/kg SAR441236 or placebo (four infusions, one every 12 weeks)

Arm B: Participants who have never taken anti-HIV medications will be assigned to one of the Dosing Groups and will receive one infusion of:

Dosing Group 5: 1 mg/kg SAR441236
Dosing Group 6: 3 mg/kg SAR441236
Dosing Group 7: 10 mg/kg SAR441236
Dosing Group 8: 30 mg/kg SAR441236

Possible Dosing Group 9: 0.3 mg/kg SAR441236

SAR441236 or placebo will be given as an intravenous infusion over 30 or 60 minutes.

On the day of the infusion, blood will be collected over 24 hours, so participants may need to stay in the clinic overnight. Participants will have blood collected for safety monitoring and the study team will determine if it's safe to open a new group at a higher dose.

Duration of Study: Most participants will be followed on study for 24 weeks after the infusion. Participants in Arm A Dosing Cohort 4, however, will be on study for 72 weeks.

For more information on this study please contact us at

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