CWRU/UH AIDS Clinical Trials Research Site
AIDS Clinical Trials Group #5359
Potential Participant Summary

A study to look at whether long-acting, injectable anti-HIV medicines are helpful for people living with HIV who have not been able to adhere with anti-HIV medicines in daily pill form

Brief Description: This study will compare the use of long-acting, injectable anti-HIV medicines with anti-HIV medicines in daily pill form for people living with HIV who have not been previously adherent (keeping up) with their anti-HIV medicines in daily pill form.

Purpose of this Study/treatment: Anti-HIV medicines taken as pills have been very successful in helping many people living with HIV to reduce their HIV viral load to very low amounts. Once these amounts get low enough, we say that the viral loads are undetectable. However, some people have not been able to take daily pills enough to get their viral loads to undetectable.

A new way of taking anti-HIV medicines has been developed. This new way, which is still in clinical trials, is giving the medicines as an injection or a shot, instead of as pills. The anti-HIV medicines given by injection last in the body for a much longer time than pills. Instead of a pill taken every day, these medicines are given by an injection once a month. This new way of giving anti-HIV medicines is called “long-acting, injectable antiretroviral therapy or LA ART”.

This study is looking at whether LA ART will be more successful for people who have not been adherent to their HIV medications when taking them in daily pill form. Taking the medicines in daily pill form is the current standard of care (SOC).

This study has 4 steps:

Step 1: 24 Weeks
During the first 24 weeks of the study, the participant’s doctor will work with the clinical trial researchers to determine which anti-HIV medicines in pill form will work best for the participant at this time. The study will provide the pills to the participant at no cost. During this period of time, the participant will work to decrease their viral load to undetectable amounts by taking pills on a daily basis (standard of care). During this step if a participant is able to reduce their viral load by a certain amount at certain visits, they will be given a financial incentive (money) in addition to the regular trial compensation. Financial incentives are given only in Step 1.

In order for a participant to move on to step 2, their viral load must reach an undetectable level (defined as below 50 copies) by the visit at week 20 and/or week 24.

Step 2: Randomization to LA ART vs. Oral SOC - 52 Weeks
Participants who move on to Step 2 will be randomly (like the flip of a coin) placed into one of two groups. One group will continue taking the same anti-HIV medicines as pills that they were taking for Step 1 for the rest of Step 2 (52 weeks). The second group will take new medicines, cabotegravir and rilpivirine, in the daily pill form for 4 weeks. After 4 weeks of pills, the participants in this group will stop taking pills and begin receiving LA ART (2 injections each month -one of cabotegravir and one of rilpivirine) for the remainder of Step 2.

Step 3: LA ART Continuation/Crossover to LA ARV - 52 weeks
Participants who receive the LA ART in Step 2 will continue to receive LA ART in Step 3. If those participants who continue to take their anti-HIV medicine in pill form throughout Step 2 maintain an undetectable viral load, at Step 3 they may switch to pills of cabotegravir and rilpivirine for 4 weeks followed by LA ART every 4 weeks for the remainder of Step 3.

Step 4: Observation on SOC for participants who received at least one dose of LA ART - 52 weeks
Any participant in this study that receives at least one dose of LA ART will be eligible to participate in Step 4. During Step 4, the participant will resume their anti-HIV medicines in pill form. These medicines will not be provided by the study.

Requirements to Enter Step 1 of the Study:
The complete list of inclusion/exclusion criteria are in the protocol, including exclusionary medications. Below is an abbreviated list of the requirements.

Inclusion:

- People living with HIV, 18 years of age and older.
- Prescribed anti-HIV medicines for at least 6 months.
- Has an HIV viral load greater than 200 copies at the screening visit.
- Women must not be pregnant, planning to become pregnant, or breastfeeding. Women who can become pregnant must agree to use 1 form of effective birth control.
- There is evidence of non-adherence to their HIV medications.

Non-adherence to HIV medications will be defined as having one of the two criteria below:

1. Poor virologic response within the last 18 months for people who have been prescribed ART for at least 6 consecutive months.

2. Lost to clinical follow-up within the last 18 months with ART non-adherence for 6 consecutive months or more. Lost to clinical follow-up is defined as either no contact with provider or missed 2 or more appointments in a 6-month period. ART non-adherence is defined as a lapse in ART 7 or more days (consecutive or non-consecutive), in the 6-month period where they were lost to clinical follow-up per participant report.

Exclusion:

- Previous use of rilpivirine or cabotegravir.
- Uncontrolled seizures.
- Advanced liver disease.
- Unwilling to receive injections in the buttocks.
- Chronic Hepatitis C with planned or anticipated use of anti-HCV therapy prior to the end of step 2.
- Active Hepatitis B infection.

Duration of Study: The study lasts between 128-180 weeks.

Compensation provided.

For more information on this study please contact us at:

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UHCMC IRB approved
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