CWRU/UH AIDS Clinical Trials Research Site
AIDS Clinical Trials Group #5391
Potential Participant Summary
Doravirine for Persons with Excessive Weight Gain
while taking Integrase Inhibitors and Tenofovir Alafenamide: 'The Do IT Study'

Brief Description: Weight gain after starting anti-HIV medicines is common, but recent studies have found that taking certain medicines may cause increased weight more than others. People living with HIV who are taking certain integrase strand transfer inhibitors (INSTI) combined with TAF/FTC (or TAF/3TC) may gain more weight than people taking other drug combinations. The INSTI that this study is looking at are bictegravir (BIC), dolutegravir (DTG) and raltegravir (RAL). *(The names and types of anti-HIV medicines can be confusing. Some "one-a-day" pills have several medicines in them. If you are not sure if your anti-HIV medicines are included in the study, the research staff can help you figure it out).*

Researchers are looking to see if people who have gained a large amount of weight after starting or switching to these INSTI-containing regimen can either reduce their rate of weight gain over time or even lose weight with a change to different anti-HIV medicines.

How it works:
People who join the trial will be randomly (like the flip of a coin) placed into one of three groups or arms. Participants will be told to which Arm they are assigned. They will stay on these anti-HIV medicines for 48 weeks.
Arm 1. Switch from current anti-HIV medicines to Doravirine plus TAF/FTC (or TAF/3TC)
Arm 2. Switch from current anti-HIV medicines to Doravirine plus TDF/FTC (or TDF/3TC)
Arm 3. Stay on current anti-HIV medicines.

Requirements to enter the study (things that must be true for all participants):

- Living with HIV and are 18 years of age or older;
- Currently taking an INSTI (BIC, DTG or RAL) as anti-HIV medicine with TAF/FTC (or TAF/3TC);
- Taking an INSTI for more than 48 weeks before study entry;
- Weight gain of more than 10% in the 1-3 years after starting (or switching to) an INSTI-based anti-HIV medicine regimen;
- Undetectable viral loads both sooner and more than 48 weeks before study entry;
- No pregnancy/breastfeeding or intention to become pregnant or breastfeed during study;
- If participants are sexually active and capable of becoming pregnant, must agree to use contraception while on study and for 8 weeks after the end of the study;
- Transgender participants taking gender-affirming hormones, must be on a stable hormone dose for more than 12 weeks prior to study entry with no plans to change hormone regimen or dose
- There are other inclusion/exclusion criteria the staff can discuss with you.

Study Products: Doravirine will be provided by the study. TAF/FTC (TAF/3TC); TDF/FTC (TDF/3TC); and INSTIs will not be provided by the study. Participants will need to receive them from their regular provider.

Duration of Study/Compensation: The study lasts for 48 weeks. Compensation provided.

For more information on this study please contact us at
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