AccessHealth MA
Formerly known as Community Research Initiative (CRI)

Define Web Summary

Trial Nickname: Define

Name: D/C/F/TAF FDC Evaluated as a Fixed Dose Combination Regimen in Participants Switching from an Integrase Inhibitor who have Experienced Rapid Weight Gain.

Participant Overview: Community Research Initiative is recruiting participants for a paid research study to evaluate the safety and tolerability of switching to a once-daily Fixed-Dose Combination regimen for those experiencing weight gain on an Integrase Inhibitor + TAF/FTC ARV regimen.

Major Eligibility Criteria:

◊ At least 18 years old

◊ Have had a suppressed viral load

◊ Have been on a stable Integrase Inhibitor + TAF/FTC ARV regimen for at least 6 months

◊ Have a proven weight gain of least 10% of your body weight

Description:

This is a randomized, 48 week, active-controlled, open-label, prospective, multicenter, Phase 4 study to evaluate the safety and tolerability of switching to D/C/F/TAF FDC compared to continuing the current INI + TAF/FTC ARV regimen in virologically-suppressed HIV-1 infected adult participants who have experienced rapid and significant body weight gain while receiving an INI + TAF/FTC ARV regimen.
The HCV study treatment and all study-required labs and exams are provided at no cost. The HCV study treatment is a 12-week, fixed-dose course of once-daily sofosbuvir/velpatasivir.

The study will consist of 3 phases: Screening (approximately 30 days [up to a maximum of 6 weeks]), Study Treatment Period (48 weeks), and Follow-up (for any participant who has an ongoing adverse event (AE) or serious adverse event (SAE) at the time of his/her last study visit).

Study Sponsor: Janssen Scientific Affairs, LLC

For more information, please contact:

Our Research Team, 617.502.1707 or info@accesshealthma.org

*Please note this Clinical Trial and Summary was started while AccessHealth MA was still known as Community Research Initiative (CRI). This information is still relevant.