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Corresponding Author Details

Family Name: Colson

First Name: Amy

Hospital/Institution: Community Research Initiative of New England

Address: 23 Miner Street

City: Boston, MA

Postal/Zip Code 02115

Country United States

Telephone 617-429-4722

Email: acolson@crine.org

Confirm Email: acolson@crine.org

Title

The FOTO Study: Twenty-Four Week Results Support the Safety of a Two Day Break on Efavirenz-Based Antiretroviral Therapy

Abstract Text

The challenges of daily antiretroviral therapy (ART) have stimulated interest in alternative treatment schedules such as short cyclical interruptions of ART in virologically suppressed patients. Short interruptions are intended to avoid rebound viremia and its negative consequences, while addressing “pill-fatigue,” cumulative long-term toxicities, and the cost associated with daily therapy.

Sixty subjects, all on daily efavirenz / tenofovir / emtricitabine (EFV/TDF/FTC) with CD4 count >200 and durable viral suppression, were randomized to continue daily therapy or change their weekly schedule to five consecutive days on treatment (typically Monday-Friday) followed by 2 days off treatment (Five-On, Two-Off, or “FOTO” schedule). HIV RNA (VL) was measured at weeks 4, 12, 24; in the FOTO arm, VL was drawn at the end of the 2-day interruption. AE, adherence, and QoL data were also collected. The primary endpoint was the proportion in each arm with virologic suppression (VL<50) at week 24. The study was powered to detect a 15% or greater difference in favor of the daily arm over the FOTO arm. Rates of virologic suppression in the two arms were compared using the Farrington-Manning test.

Thirty were enrolled on each arm. Baseline characteristics were similar in the two arms (15% women; mean age 45; mean CD4 count 663). Fifty-three completed 24 weeks on study: 25 on FOTO and 28 on daily treatment. All 7 who stopped prior to week 24 had an HIV RNA < 50 at the time of study discontinuation. There were 6 blips (VL 50 – 500) in the FOTO arm and 9 blips in the daily arm through week 24. There was no virologic failure (confirmed VL>400) through week 24. By intent-to-treat analysis (drop out=failure), 83% (95% CI: 70-97) on FOTO versus 80% (95% CI: 66-94) on daily treatment had an HIV RNA < 50 at week 24. By as-treated analysis, 100% (95% CI: 88-100) on FOTO versus 86% (95% CI: 73-99) on daily treatment had a VL < 50 at

week 24. Week 24 suppression rates were equivalent in the two groups ($p < 0.005$) by the Farrington-Manning test. There were three reported neuropsychiatric AEs: two on FOTO and one on daily; all were judged mild.

These data confirm the success of a Five-day on / Two-day off strategy for maintaining virologic suppression for at least 24 weeks on EFV/TDF/FTC. Follow up is ongoing to further assess durability. This treatment strategy could significantly reduce antiretroviral drug costs, which is especially important in resource scarce areas

References

Submission Category

01F Treatment Strategies - Simplification

Presentation preference

Oral or Poster

Authors

Cohen, C., Community Research Initiative of New England, Boston, MA, United States, ccohen@crine.org (Presenting); Colson, A., Community Research Initiative of New England, Boston, MA, United States, acolson@crine.org; Pierone, G., AIDS Research and Treatment Center of the Treasure Coast, Fort Pierce, FL, United States, pieroneg@verocma.com; DeJesus, E., Orlando Immunology Center, Orlando, FL, United States, edejesus@oicorlando.com; Kinder, F., Kinder Medical Group, Miami, FL, United States, kinderdoc@aol.com; Elion, R., Whitman-Walker Clinic, Washington, DC, United States, drrelion@aol.com; Skiest, D., Community Research Initiative of New England, Springfield, MA, United States, dskiest@crine.org; Habel, A., Community Research Initiative of New England, Boston, MA, United States, ahabel@crine.org; Jensen, J., Community Research Initiative of New England, Boston, MA, United States, jjensen@crine.org; Garb, J., Baystate Medical Center, Springfield, MA, United States, jane.garb@verizon.net; Schrager, H., Community Research Initiative of New England, Boston, MA, United States, hschrager@crine.org