

Oral presentation

O214 The FOTO study: 24-week results support the safety of a 2-day break on efavirenz-based antiretroviral therapy

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Background

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.

Methods

60 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 5 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.

Summary of results

30 were enrolled on each arm. Baseline characteristics were similar in the two arms (15% women; mean age 45

years; mean CD4 count 663). Fifty-three completed 24 weeks on study: 25 on FOTO and 28 on daily treatment. All seven who stopped prior to week 24 had an HIV-RNA <50 at the time of study discontinuation. There were six blips (VL 50 – 500) in the FOTO arm and nine 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 vs. 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 vs. 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.

Conclusion

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.