

Switch to Elvitegravir-Cobicistat-Tenofovir DF-Emtricitabine Study 123



Switch to Elvitegravir-Cobicistat-Tenofovir DF-Emtricitabine Study 123: Study Design

- Background: Open-label, randomized phase 3b trial evaluating switching to once-daily elvitegravir-cobicistat-tenofovir DFemtricitabine from twice daily raltegravir plus tenofovir DF-emtricitabine
- Inclusion Criteria (n = 48)
 - HIV RNA <50 copies/mL
 - On RAL+ TDF-FTC for ≥6 months
 - Not taking any other ART
 - No new AIDS-defining conditions
- Treatment Arms
 - Switch to EVG-COBI-TDF-FTC





Switch to Elvitegravir-Cobicistat-Tenofovir DF-Emtricitabine Study 123: Results

Virologic Response After Switch to EVG-COBI-TDF-FTC





Source: Mills A, et al. HIV Clin Trials. 2014;15:51-6.

Switch to Elvitegravir-Cobicistat-Tenofovir DF-Emtricitabine Study 123: Common Adverse Events

Treatment Emergent Adverse Events in ≥ 10% of Subjects

| Adverse Event (treatment emergent) | Switched to EVG-COBI-TDF-FTC (n = 48) |
|---------------------------------------|--|
| Upper Respiratory Tract Infection | 21% |
| Insomnia | 13% |
| Diarrhea | 10% |
| Fatigue | 10% |
| Anxiety | 10% |

Source: Mills A, et al. HIV Clin Trials. 2014;15:51-6.



Switch to Elvitegravir-Cobicistat-Tenofovir DF-Emtricitabine Study 123: Conclusions

Conclusion: "All participants switching to 1 tablet once-a-day elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (*Stribild*) from a twicedaily raltegravir + emtricitabine/tenofovir disoproxil fumarate regimen remained virologically suppressed. *Stribild* was well tolerated. Switching to *Stribild* may be a viable option for virologically suppressed patients wanting to simplify from a twicedaily raltegravir-containing regimen."



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