Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC

Study 104
### Study Design: Study 104

**Background:** Randomized, double-blind, double dummy, phase 2 trial comparing elvitegravir-cobicistat-tenofovir DF-emtricitabine with efavirenz-tenofovir DF-emtricitabine

**Inclusion Criteria (n = 71)**
- Antiretroviral-naïve patients
- Age ≥ 18
- HIV RNA ≥ 5,000 copies/ml
- CD4 count > 50 cells/mm³

**Treatment Arms**
- Elvitegravir-Cobicistat-TDF-FTC
- Efavirenz-TDF-FTC

**Study Design:**

- **Elvitegravir-Cobicistat-TDF-FTC QD** (n = 48)
- **Efavirenz-TDF-FTC QD** (n = 23)

Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC

Study 104: Result

Week 24 and 48: Virologic Response (ITT Analysis, M=F)

Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC

Study 104: Adverse Effects

Drug-Related, Treatment-Emergent Adverse Effects

Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC
Study 104: Adverse Effects

Change in Estimated Glomerular Filtration Rate (Cockcroft-Gault)

Mean Change in Estimated GFR (ml/min)

<table>
<thead>
<tr>
<th>Week 2</th>
<th>Week 24</th>
<th>Week 48</th>
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</thead>
<tbody>
<tr>
<td>Efavirenz-TDF-FTC</td>
<td>-1.1</td>
<td>-6.6</td>
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Interpretation: “Once-daily elvitegravir/cobicistat/emtricitabine/tenofovir (EVG/COBI/FTC/TDF) achieved and maintained a high rate of virologic suppression with fewer central nervous system and psychiatric adverse events compared to a current standard-of-care regimen of efavirenz/emtricitabine/tenofovir (EFV/FTC/TDF).”
Acknowledgment

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*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*