EFV + TDF + FTC versus EFV + ZDV-3TC

Study 934
**Study Design: STUDY 934**

- **Background**: Randomized, open label phase 3 study comparing efavirenz plus either tenofovir DF and emtricitabine or fixed-dose zidovudine-lamivudine

- **Inclusion Criteria (n = 509)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥10,000 copies/mL
  - CD4 >50 cells/mm³
  - No AIDS conditions in prior 30 days

- **Treatment Arms**
  - Efavirenz + tenofovir DF + emtricitabine
  - Efavirenz + zidovudine-lamivudine

**Study 934: Study Design**

**EFV QD + TDF + FTC QD (n = 255)**

**EFV QD + ZDV-3TC BID (n = 254)**

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC
Study 934: Result

Week 48: Virologic Response (< 400 copies/mL)

![Graph showing virologic response](image)

**ITT Population**
- EFV + TDF + FTC: 81/206 (77.6%) vs. EFV + ZDV-3TC: 70/177 (39.4%)

**Excluding NNRTI-R**
- EFV + TDF + FTC: 84/206 (41.1%) vs. EFV + ZDV-3TC: 73/177 (41.7%)

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC

Study 934: Result

Week 48: Virologic Response (<50 copies/mL)


ITT = Intention-to-Treat; NNRTI-R = Patients with baseline NNRTI mutations.
Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC

Study 934: Result

Week 48: Immunologic Response

Mean Change in CD4 count (cells/mm$^3$)

- EFV + TDF + FTC: 190
- EFV + ZDV-3TC: 158

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC

Study 934: Result

Adverse Events through 48 Weeks

### Treatment Emergent Adverse Events in ≥ 5% of Subjects in Either Arm

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>EFV + TDF + FTC (n = 257)</th>
<th>EFV + ZVD-3TC (n = 254)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dizziness</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>Nausea</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Depression</td>
<td>4%</td>
<td>7%</td>
</tr>
<tr>
<td>Headache</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Rash</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Anemia</td>
<td>&lt;1%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Interpretation: “Through week 48, the combination of tenofovir DF and emtricitabine plus efavirenz fulfilled the criteria for noninferiority to a fixed dose of zidovudine and lamivudine plus efavirenz and proved superior in terms of virologic suppression, CD4 response, and adverse events resulting in discontinuation of the study drugs.”

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