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

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

• **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

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

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

<table>
<thead>
<tr>
<th>Study Populations</th>
<th>EFV + TDF + FTC</th>
<th>EFV + ZDV-3TC</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT Population</td>
<td>206/255</td>
<td>177/254</td>
</tr>
<tr>
<td></td>
<td>81</td>
<td>70</td>
</tr>
<tr>
<td>Excluding NNRTI-R</td>
<td>206/244</td>
<td>177/243</td>
</tr>
<tr>
<td></td>
<td>84</td>
<td>73</td>
</tr>
</tbody>
</table>

Abbreviations: ITT = Intention-to-Treat; NNRTI-R = Patients with baseline NNRTI mutations.

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

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


**Abbreviations:** ITT = Intention-to-Treat; NNRTI-R = Patients with baseline NNRTI resistance mutations.
Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC
Study 934: Results

Week 48: Immunologic Response

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

Adverse Events Through 48 Weeks

Patients Who Experienced Adverse Events (%)

Adverse Event

63

Adverse Event Leading to Discontinuation

EFV + TDF + FTC

EFV + ZDV-3TC

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

## Study 934: Common Adverse Events

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Events in ≥ 5% of Subjects in Either Arm</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.”

The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.