EFV + TDF + FTC versus EFV + ZDV-3TC
Study 934
Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC

Study 934: Study Design

**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

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

Study 934: Result

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

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

![Graph showing mean change in CD4 count (cells/mm³) between EFV + TDF + FTC and EFV + ZDV-3TC.]

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

Study 934: Result

Adverse Events through 48 Weeks

# 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 an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.

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