Simplification to Efavirenz-TDF-FTC

STUDY 073
Simplification to Efavirenz-TDF-FTC
Study 073: Design

**Study Design: Study 073**

- **Background**: Randomized, controlled, open label phase 3 trial evaluating a simplification strategy for patients suppressed on baseline ART by switching to a single-tablet regimen of efavirenz-tenofovir DF-emtricitabine once daily.

- **Inclusion Criteria (n = 300)**
  - Age ≥ 18
  - HIV RNA ≤ 200 copies/mL for ≥ 3 months
  - No new AIDS-defining conditions in past 30d
  - On 1st ART regimen or viral suppression on previous protease inhibitor-based therapy at time of prior therapy switch

- **Treatment Arms**
  - Switch arm: Efavirenz-tenofovir DF-emtricitabine
  - Stay arm: maintain baseline ART

**Switch arm**
Efavirenz-TDF-FTC QD
(n = 203)

**Maintain arm**
Stay on Baseline ART
(n = 97)

Simplification to Efavirenz-TDF-FTC
Study 073: Result

Week 48 Virologic Response by RNA Threshold

Simplification to Efavirenz-TDF-FTC
Study 073: Subgroup Analysis Result

Week 48 Virologic Response, by Baseline Regimen (ITT Analysis, NC=F)

HIV RNA < 50 copies/mL (%)

- **EFV-TDF-FTC (switch arm)**
- **Baseline ART (maintain arm)**

<table>
<thead>
<tr>
<th>Category</th>
<th>EFV-TDF-FTC</th>
<th>Baseline ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>All prior regimens</td>
<td>87/97</td>
<td>85/97</td>
</tr>
<tr>
<td>Prior NNRTI</td>
<td>92/95</td>
<td>82/45</td>
</tr>
<tr>
<td>Prior PI</td>
<td>83/108</td>
<td>87/52</td>
</tr>
</tbody>
</table>

Interpretation: “Simplification to EFV/FTC/TDF maintained high and comparable rates of virologic suppression versus stay on baseline regimen (SBR) through 48 weeks.”

Simplification to Efavirenz-TDF-FTC
Study 073: Patient-Reported Outcomes

Week 48: Perceived Ease of Medication Scores

Subjects (%) Reporting Regimen “very easy” to follow

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Reporting Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFV-TDF-FTC (switch arm)</td>
<td>97/173</td>
</tr>
<tr>
<td>Baseline ART (maintain arm)</td>
<td>81/70</td>
</tr>
</tbody>
</table>

Simplification to Efavirenz-TDF-FTC
Study 073: Patient-Reported Outcomes

Week 48: Medication Preference Scores of EFV-TDF-FTC

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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