Switch from EFV plus ABC-3TC to EFV-TDF-FTC

ROCKET-1 Trial
Switch from EFV + ABC-3TC to EFV-TDF-FTC

ROCKET-1: Design

Study Design: ROCKET Study

- **Background**: Randomized, open label, phase 4 trial to assess the effect on lipid profile of switching from EFV plus ABC-3TC to EFV-TDF-FTC in hypercholesterolemic adults with HIV

- **Inclusion Criteria (n = 157)**
  - Age >18 years
  - On EFV plus ABC-3TC for ≥3 months
  - HIV RNA <50 copies/mL
  - Total cholesterol >200 mg/dL x 2 consecutive tests (at least 4 weeks apart)
  - No resistance to study drugs

- **Treatment Arms**
  - Efavirenz-tenofovir DF-emtricitabine
  - Efavirenz plus abacavir-lamivudine x 12 weeks, then efavirenz-tenofovir DF-emtricitabine

Immediate switch arm
EFV-TDF-FTC
(n = 79)

Delayed switch arm
EFV + ABC-3TC x 12 weeks, then EFV-TDF-FTC
(n = 78)

Switch from EFV + ABC-3TC to EFV-TDF-FTC
ROCKET-1: Result

Week 12: Virologic Response (Intent-to-Treat Analysis)

Switch from EFV + ABC-3TC to EFV-TDF-FTC

ROCKET-1: Result

Week 12: Changes in Lipid Fractions (Treated Analysis Set)

Baseline for Delayed switch arm was reset at week 12 (prior to switch to EFV-TDF-FTC)

Median Change from Baseline (mmol/L)

<table>
<thead>
<tr>
<th></th>
<th>Continuation arm</th>
<th>Delayed switch arm</th>
<th>Immediate switch arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>-0.73</td>
<td>-0.86</td>
<td>-0.61</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>0.01</td>
<td>-0.02</td>
<td>0.00</td>
</tr>
<tr>
<td>HDL</td>
<td>-0.13</td>
<td>-0.26</td>
<td>-0.14</td>
</tr>
<tr>
<td>LDL</td>
<td>0.04</td>
<td>-0.14</td>
<td>-0.13</td>
</tr>
</tbody>
</table>

Switch from EFV + ABC-3TC to EFV-TDF-FTC
ROCKET-1: Result

Fasting Total Cholesterol by NCEP Thresholds

![Graph showing fasting total cholesterol levels by NCEP thresholds across baseline, week 12, and week 24 for patients in the immediate switch arm.](image)

- **Baseline**: 6% <5.2 mmol/L, 29% 5.2-6.2 mmol/L, 65% >6.2 mmol/L
- **Week 12**: 6% <5.2 mmol/L, 25% 5.2-6.2 mmol/L, 43% >6.2 mmol/L
- **Week 24**: 6% <5.2 mmol/L, 28% 5.2-6.2 mmol/L, 42% >6.2 mmol/L

Switch from EFV + ABC-3TC to EFV-TDF-FTC
ROCKET-1: Result

Fasting Total Cholesterol by NCEP Thresholds

Switch from EFV + ABC-3TC to EFV-TDF-FTC

ROCKET-1: Result

Fasting Total Cholesterol by NCEP Thresholds

Immediate Switch Arm (12 weeks on EFV-TDF-FTC)
- <5.2 mmol/L (desirable): 28%
- 5.2-6.2 mmol/L (borderline): 42%
- > 6.2 mmol/L (above goal): 30%

Delayed Switch Arm (12 weeks on EFV-TDF-FTC)
- <5.2 mmol/L (desirable): 40%
- 5.2-6.2 mmol/L (borderline): 47%
- > 6.2 mmol/L (above goal): 13%

Interpretation: "Switching from ABC/3TC+EFV to EFV/FTC/TDF in persons with hypercholesterolemia maintains virological control and significantly improves key lipid parameters."
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.

*The content in this presentation 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.*