Efavirenz 400 mg versus 600 mg, with TDF-FTC
ENCORE1 Trial
Efavirenz 400 mg versus Efavirenz 600 mg, with TDF-FTC

ENCORE1: Study Design

**Study Design: ENCORE1**

- **Background**: Randomized, double-blind, placebo-controlled study comparing the safety and efficacy of two doses of efavirenz, in combination with co-formulated tenofovir DF and emtricitabine

- **Inclusion Criteria (n = 636)**
  - Antiretroviral-naïve
  - Age ≥16 years
  - HIV RNA ≥1000 copies/mL
  - CD4 count >50 and <500 cells/mm$^3$

- **Treatment Arms**
  - Efavirenz 400 mg QD + TDF-FTC QD
  - Efavirenz 600 mg QD + TDF-FTC QD

Efavirenz 400 mg versus Efavirenz 600 mg, with TDF-FTC

ENCORE1: Results

Week 48: Virologic Response (Modified Intention-to-Treat)

Efavirenz 400 mg versus Efavirenz 600 mg, with TDF-FTC
ENCORE1: Results

<table>
<thead>
<tr>
<th>Overall Adverse Events</th>
<th>EFV 400 mg n (%)</th>
<th>EFV 600 mg n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Variable</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of adverse events</td>
<td>1173 (49.8%)</td>
<td>1182 (50.2%)</td>
</tr>
<tr>
<td><strong>Serious adverse events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of serious adverse events</td>
<td>31 (46.2%)</td>
<td>36 (53.7%)</td>
</tr>
<tr>
<td>Number with serious adverse events</td>
<td>23 (7.17%)</td>
<td>22 (7.12%)</td>
</tr>
<tr>
<td>Number with serious adverse events related to study drug</td>
<td>3 (0.93%)</td>
<td>4 (1.29%)</td>
</tr>
<tr>
<td><strong>Adverse events probably related to study drug</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with adverse events related to study drug</td>
<td>118 (36.8%)</td>
<td>146 (47.2%)</td>
</tr>
<tr>
<td>Patients stopping drug due to drug related adverse event</td>
<td>6 (1.9%)</td>
<td>18 (5.8%)</td>
</tr>
</tbody>
</table>

Efavirenz 400 mg versus Efavirenz 600 mg, with TDF-FTC

ENCORE1: Conclusions

Interpretation: “Our findings suggest that a reduced dose of 400 mg efavirenz is non-inferior to the standard dose of 600 mg, when combined with tenofovir and emtricitabine during 48 weeks in ART-naive adults with HIV-1 infection. Adverse events related to the study drug were more frequent with 600 mg efavirenz than with 400 mg. Lower dose efavirenz should be recommended as part of routine care.”

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