Effects of Switching ZDV to TDF on Fat Distribution and Lipoatrophy

RECOMB
Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Fat Distribution): Study Design

**Study Design: RECOMB**

- **Background**: Prospective, randomized, open-label, multicenter trial conducted in Spain comparing effect of continuation of ZDV-3TC versus switching to TDF-FTC on limb fat mass and other laboratory parameters.

- **Inclusion Criteria**:
  - Adults with HIV infection
  - Receiving a cART regimen including ZDV and 3TC* plus an NNRTI or PI for ≥6 months
  - HIV RNA <50 copies/mL at last two consecutive checks

- **Regimens**
  - Switch ZDV-3TC to TDF-FTC
  - Continue ZDV-3TC

**Switch Arm**
Tenofovir DF-Emtricitabine  
(n = 39)

**Continuation Arm**
Zidovudine + Lamivudine*
(n = 41)

*Either as fixed-dose zidovudine-lamivudine or as separate zidovudine and lamivudine tablets.

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RECOMB (Fat Distribution): Results

Change in Limb Fat Mass from Baseline (Measured by DXA)

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RECOMB (Fat Distribution): Results

Week 72: Change in Plasma Lipids

## Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

### RECOMB (Fat Distribution): Results

**Week 72: Change in Laboratory Parameters from Baseline**

<table>
<thead>
<tr>
<th>Laboratory Results: Change from Baseline to Week 72 (Median Values)</th>
<th>TDF-FTC</th>
<th>ZDV-3TC</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trunk fat content (kg)</td>
<td>0.354</td>
<td>0.526</td>
<td>0.897</td>
</tr>
<tr>
<td>Total body fat (kg)</td>
<td>0.786</td>
<td>0.334</td>
<td>0.307</td>
</tr>
<tr>
<td>Haemoglobin (g/dL)</td>
<td>1.0</td>
<td>-0.1</td>
<td>0.0002</td>
</tr>
<tr>
<td>Hematocrit (%)</td>
<td>2.3</td>
<td>0.0</td>
<td>0.0014</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.05</td>
<td>-0.02</td>
<td>0.001</td>
</tr>
<tr>
<td>Lactic acid (mmol/L)</td>
<td>-0.17</td>
<td>0.07</td>
<td>0.024</td>
</tr>
</tbody>
</table>

Conclusions: “Switching from a ZDV/3TC-based to a TDF/FTC-based regimen led to a statistically significant improvement in limb fat, in contrast to the progressive loss of limb fat in subjects continuing ZDV/3TC.”
Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Lipoatrophy): Study Design

**Study Design: RECOMB**

- **Background**: Prospective, randomized, open-label, multicenter trial conducted in Spain comparing effect of continuation of ZDV-3TC versus switching to TDF-FTC on fat mass ratio (FMR), an indicator of fat distribution (lipoatrophy defined as FMR ≥1.5)

- **Inclusion Criteria**:
  - HIV-infected men enrolled in the RECOMB study (women excluded because FMR cutoff values for women not defined)
  - Receiving a cART regimen including ZDV and 3TC* plus an NNRTI or PI for ≥6 months
  - HIV RNA <50 copies/mL at last two consecutive checks

- **Regimens**
  - Switch ZDV-3TC to TDF-FTC
  - Continue ZDV-3TC

**Switch Arm**
- Tenofovir DF-Emtricitabine
  - (n = 28)

**Continuation Arm**
- Zidovudine + Lamivudine*
  - (n = 37)

*Either as fixed-dose zidovudine-lamivudine or as separate zidovudine and lamivudine tablets

Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Lipoatrophy): Results

Change in Fat Mass Ratio (FMR) from Baseline (All Subjects)

Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Lipoatrophy): Results

Change in FMR from Baseline (Subjects with FMR ≥ 1.5 at Study Entry)

Conclusions: “Switching from ZDV/3TC to FTC/TDF led to an improvement in FMR, compared with progressive worsening of FMR in subjects receiving ZDV/3TC, showing that fat mass not only increased but was also distributed in a healthier way after the switch.”
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.

The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.