Switch to Dolutegravir-Lamivudine versus Continued TAF-Based 3-Drug ART

TANGO
Switch to DTG-3TC versus Continued TAF-Based Baseline Regimen
TANGO: Design

**Design:** Open-label, non-inferiority trial in adults with suppressed HIV RNA while taking a 3- or 4-drug tenofovir alafenamide (TAF)-based regimen, randomized to switch to fixed-dose dolutegravir-lamivudine (DTG-3TC) or continue the baseline regimen.

**Inclusion Criteria**
- Adults with suppressed HIV RNA >6 months
- Taking 3- or 4-drug TAF-based ART
- No history of virologic failure
- No major NRTI resistance; no INSTI resistance
- No hepatitis B or C

**Regimens**
- Dolutegravir-lamivudine (50/300mg) daily
- TAF-based 3- or 4-drug baseline regimen

**Switch Group**
Dolutegravir-Lamivudine
(n = 369)

**Continue Baseline Regimen Group**
TAF-Based 3- or 4-Drug Regimen
(n = 372)

Switch to DTG-3TC versus Continued TAF-Based Baseline Regimen
TANGO: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Dolutegravir-Lamivudine (n = 369)</th>
<th>TAF-Based ART (n = 372)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, median (range)</td>
<td>40 (20-74)</td>
<td>39 (18-73)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>25 (7)</td>
<td>33 (9)</td>
</tr>
<tr>
<td>White, n (%)</td>
<td>297 (81)</td>
<td>289 (78)</td>
</tr>
<tr>
<td>African American/African, n (%)</td>
<td>50 (14)</td>
<td>58 (16)</td>
</tr>
<tr>
<td>CD4 cell count &lt;500, n (%)</td>
<td>98 (27)</td>
<td>74 (20)</td>
</tr>
<tr>
<td>CD4 cell count ≥500, n (%)</td>
<td>271 (73)</td>
<td>298 (80)</td>
</tr>
<tr>
<td>Months on ART, median (range)</td>
<td>33.8 (7.1-201.2)</td>
<td>35.1 (7.0-160.8)</td>
</tr>
<tr>
<td>Baseline third agent class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INSTI</td>
<td>289 (78)</td>
<td>296 (80)</td>
</tr>
<tr>
<td>NNRTI</td>
<td>51 (14)</td>
<td>48 (13)</td>
</tr>
<tr>
<td>PI</td>
<td>29 (8)</td>
<td>28 (8)</td>
</tr>
</tbody>
</table>

Switch to DTG-3TC versus Continued TAF-Based Baseline Regimen
TANGO: Results at Week 48

Week 48 Virologic Response (Intention-to-Treat Snapshot Analysis)

- Confirmed withdrawal for virologic failure: 0 in DTG/3TC arm, 1 in TAF-based ART arm
- No new resistance mutations occurred
- 4 with baseline M184V/I in DTG/3TC arm (by proviral genotype) suppressed at week 48

Switch to DTG-3TC versus Continued TAF-Based Baseline Regimen
TANGO: Results at Week 48

Week 48 Changes in Renal Function (Plasma/Serum Markers)

Switch to DTG/3TC vs Continued TAF-Based 3-Drug ART
TANGO: Results at Week 48

Week 48 Changes in Markers of Proximal Tubulopathy (Urine Tests)

<table>
<thead>
<tr>
<th>Marker to Creatinine</th>
<th>Change from Baseline, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>-2.9</td>
</tr>
<tr>
<td>Retinol-binding protein</td>
<td>6.3</td>
</tr>
<tr>
<td>Beta-2 microglobulin</td>
<td>-2.7</td>
</tr>
</tbody>
</table>

Switch to DTG-3TC versus Continued TAF-Based Baseline Regimen

TANGO: Conclusions

Conclusion: “Dolutegravir-lamivudine was noninferior in maintaining virologic suppression vs a TAF-based regimen at week 48, with no virologic failure or emergent resistance reported with DTG/3TC, supporting it as a simplification strategy for virologically suppressed people with HIV-1.”

Switch to DTG-3TC versus Continued TAF-Based Baseline Regimen
TANGO: 144 Week Results

Week 144 Virologic Response (ITT-Exposed)

Conclusion: “The 2-drug regimen dolutegravir-lamivudine was non-inferior in maintaining virologic suppression vs a tenofovir alafenamide-based regimen at Week 48, with no virologic failure or emergent resistance reported in the dolutegravir-lamivudine group, supporting its use as a simplification strategy for virologically suppressed people living with HIV-1.”

The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents 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. For more information, please visit HRSA.gov. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.