Switch to DTG + 3TC versus Continued 3-Drug ART

ASPIRE
Switch to DTG + 3TC versus Continued 3-Drug Antiretroviral Therapy

**ASPIRE: Background**

- **Background**: Open-label, multicenter, pilot randomized trial that enrolled persons with suppressed HIV RNA levels and compared switch to 2-drug regimen versus continuing standard 3-drug antiretroviral therapy.

- **Inclusion Criteria**:
  - Adults (age >18 years) with HIV
  - HIV RNA <50 copies/mL at least twice over 48 weeks
  - Screening HIV RNA <20 copies/mL
  - Taking any 3-drug ART regimen
  - No history of virologic failure
  - No known NRTI or INSTI resistance mutations
  - No chronic HBV
  - CrCl ≥50 mL/min

**Switch Group**

Dolutegravir + Lamivudine  
(n = 44)

**Continue Group**

Continue 3-drug ART  
(n = 45)

### ASPIRE: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Combined Group Study Population (n = 89)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, median (IQR)</td>
<td>47 (38-54)</td>
</tr>
<tr>
<td>Male, %</td>
<td>88</td>
</tr>
<tr>
<td>White, %</td>
<td>60</td>
</tr>
<tr>
<td>Black or African American, %</td>
<td>38</td>
</tr>
<tr>
<td>Hispanic ethnicity, %</td>
<td>15</td>
</tr>
<tr>
<td>CD4 count, cells/mm³, median (IQR)</td>
<td>680 (498-927)</td>
</tr>
<tr>
<td>Time on ART, years, median (IQR)</td>
<td>5.7 (3.7-7.5)</td>
</tr>
<tr>
<td>Pre-randomization INSTI, %</td>
<td>37</td>
</tr>
<tr>
<td>Pre-randomization PI, %</td>
<td>33</td>
</tr>
<tr>
<td>Pre-randomization NNRTI, %</td>
<td>30</td>
</tr>
</tbody>
</table>

Switch to DTG + 3TC versus Continued 3-Drug Antiretroviral Therapy
ASPIRE: Results at 24 & 48 Weeks

Week 24 & 48 Virologic Responses (Intention-to-Treat Analysis)

One virologic failure occurred in the dolutegravir + lamivudine arm; no resistance mutations detected

Conclusion: “In this randomized pilot clinical trial, dolutegravir plus lamivudine was noninferior to continuation of standard 3-drug maintenance antiretroviral therapy. There was no emergence of drug resistance in the participant who experienced virologic failure while receiving dolutegravir plus lamivudine.”

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.