DTG + 3TC Maintenance ART vs. Continued 3-Drug ART

ASPIRE
DTG + 3TC Maintenance ART vs Continued 3-Drug ART

ASPIRE: Background


Study Design: ASPIRE

• **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 living with HIV
  - HIV RNA <50 copies/mL ≥2x 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 mutations
  - No chronic HBV
  - CrCl ≥50 mL/min

Dolutegravir + Lamivudine
(n = 44)

Continue 3-drug ART
(n = 45)
## ASPIRE: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall 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/mm$^3$, 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>

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ASPIRE: Results

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.”
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