Dolutegravir + Lamivudine as Maintenance Dual Therapy

LAMIDOL
Dolutegravir plus Lamivudine as Maintenance Dual Therapy

LAMIDOL: Design

**Study Design: LAMIDOL**

- **Background**: Non-comparative, open-label, single-arm, multicenter trial to evaluate the efficacy and tolerance of once daily dolutegravir plus lamivudine as maintenance dual therapy

- **Inclusion Criteria**:
  - Age ≥18 years
  - Nadir CD4 count >200 cells/mm³
  - HIV RNA <50 copies/mL for ≥2 years
  - Wild-type baseline genotype
  - First-line 3-drug ART:
    - 2 NRTI’s + NNRTI, boosted PI, or INSTI
  - Prior modifications for intolerance or simplification allowed
  - No HBV co-infection

- **Regimen (Once daily)**
  - Dolutegravir 50 mg + Lamivudine 300 mg

---

**Phase 1**
- 8 weeks

**Phase 2**
- 40 weeks

*Phase 1: third agent switched to dolutegravir

**Phase 2: 2NRTIs switched to lamivudine

**Dolutegravir plus Lamivudine as Maintenance Dual Therapy**

**LAMIDOL: Baseline Characteristics**

<table>
<thead>
<tr>
<th>Participants who Entered Phase 2</th>
<th>Dolutegravir-Lamivudine n = 104</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median)</td>
<td>45 years</td>
</tr>
<tr>
<td>Male</td>
<td>89 (85.6%)</td>
</tr>
<tr>
<td>MSM</td>
<td>73 (70.2%)</td>
</tr>
<tr>
<td>Duration since HIV diagnosis (median)</td>
<td>6.3 years</td>
</tr>
<tr>
<td>Time on current ART (median)</td>
<td>4.0 years</td>
</tr>
<tr>
<td>Nadir CD4 count (median)</td>
<td>399 cells/mm$^3$</td>
</tr>
<tr>
<td>Current CD4 count (median)</td>
<td>743 cells/mm$^3$</td>
</tr>
<tr>
<td>Baseline NNRTI</td>
<td>58 (55.8%)</td>
</tr>
<tr>
<td>Baseline PI</td>
<td>24 (23.1%)</td>
</tr>
<tr>
<td>Baseline INSTI</td>
<td>22 (21.2%)</td>
</tr>
</tbody>
</table>

Dolutegravir plus Lamivudine as Maintenance Dual Therapy
LAMIDOL: Results

Week 48 Virologic Response (by FDA Snapshot Analysis)


*Other 3 participants:
- 1 with low-level viremia (resuppressed with 3-drug antiretroviral therapy),
- 1 treatment modification decided by investigator, and
- 1 lost to follow-up
**Conclusion**: “Dolutegravir plus lamivudine is a promising maintenance therapy in HIV-1-infected patients with controlled virological suppression.”

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.

*The content in this presentation 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.*