Dolutegravir as Maintenance Monotherapy

DOMONO
Dolutegravir as Maintenance Monotherapy

DOMONO: Design

**Study Design: DOMONO**

- **Background**: Randomized, open-label, phase 2, non-inferiority trial conducted at 2 centers in Netherlands to determine if dolutegravir monotherapy is noninferior to combination antiretroviral therapy in maintaining viral suppression.

- **Inclusion Criteria:**
  - Age ≥18 years old
  - On 3-drug ART
  - HIV RNA <50 copies/mL for ≥6 months
  - HIV RNA zenith <100,000 copies/mL
  - CD4 count nadir >200 cells/mm³
  - No baseline HIV drug resistance
  - No history of virologic failure
  - No HBV co-infection

- **Dolutegravir Regimen**
  - Dolutegravir 50 mg once daily

**Immediate Switch to Monotherapy**
- **Dolutegravir**
  - (n = 51)

**Continue 3-Drug ART**
- (n = 53)

**Delayed Monotherapy**
- **Dolutegravir**
  - (n = 47)
  - 6/53 did not switch

**Separate Control Group**
- **3-Drug ART**
  - (n = 152)

**Source:** Wijting I, et al. Lancet HIV. 2017;4;e547-54.
Dolutegravir as Maintenance Monotherapy
DOMONO: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Immediate Switch to DTG Monotherapy (n = 51)</th>
<th>Delayed Switch to DTG Monotherapy (n = 53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median, years)</td>
<td>46</td>
<td>45</td>
</tr>
<tr>
<td>Male, %</td>
<td>47</td>
<td>48</td>
</tr>
<tr>
<td>MSM, %</td>
<td>80</td>
<td>77</td>
</tr>
<tr>
<td>Caucasian ethnicity, %</td>
<td>86</td>
<td>79</td>
</tr>
<tr>
<td>On TDF before switch, %</td>
<td>86</td>
<td>85</td>
</tr>
<tr>
<td>On NNRTI + 2 NRTI’s before switch, %</td>
<td>80</td>
<td>81</td>
</tr>
<tr>
<td>On PI + 2 NRTI’s before switch, %</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>On INSTI + 2 NRTI’s before switch, %</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>Receiving a STR before switch, %</td>
<td>63</td>
<td>77</td>
</tr>
<tr>
<td>Time on ART (median, months)</td>
<td>35</td>
<td>43</td>
</tr>
<tr>
<td>HIV RNA zenith (median, copies/mL)</td>
<td>29,300</td>
<td>44,877</td>
</tr>
<tr>
<td>CD4 T-cell nadir (median, cells/mm³)</td>
<td>320</td>
<td>380</td>
</tr>
</tbody>
</table>

Dolutegravir as Maintenance Monotherapy
DOMONO: 24-Week Results

Week 24 Virologic Suppression

Dolutegravir as Maintenance Monotherapy
DOMONO: 48-Week Results

Week 48 Virologic Suppression (Entire Study Population)

- Study stopped early; 8 virologic failures in dolutegravir arm, 3 with INSTI resistance (N155H, R263K, S230R)
- RNA at failure 678-4,990 copies/mL with one exception (71,600 copies/mL); all reported >95% adherence and all suppressed with re-initiation of cART

**Interpretation**: “Dolutegravir monotherapy was non-inferior to combination ART at 24 weeks. However, virological failure continued to occur thereafter and led to dolutegravir resistance. Dolutegravir should not be used as maintenance monotherapy.”

**Source**: Wijting I, et al. Lancet HIV. 2017;4;e547-54.
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.

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