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 non-inferior 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 Monotherapy**
- Dolutegravir (n = 51)

**Continue 3-Drug ART**
- Continue 3-Drug ART (n = 53)
  - 6/53 did not switch

**Delayed Monotherapy**
- Dolutegravir (n = 47)

**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>

**Source:** Wijting I, et al. Lancet HIV. 2017;4;e547-54.
Dolutegravir as Maintenance Monotherapy
DOMONO: 24-Week Results

Week 24 Virologic Suppression

HIV RNA <200 copies/mL (%)

<table>
<thead>
<tr>
<th>Condition</th>
<th>n</th>
<th>HIV RNA &lt;200 copies/mL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolutegravir Monotherapy (n=50*)</td>
<td>49</td>
<td>98</td>
</tr>
<tr>
<td>3-Drug ART (n=53)</td>
<td>53</td>
<td>100</td>
</tr>
</tbody>
</table>

*One of 51 participants in the immediate DTG switch arm discontinued treatment after 12 weeks because of disturbed sleep (HIV RNA <50 copies/mL at the time)

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.”
Acknowledgment

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