Dolutegravir + ABC-3TC and CSF HIV-1 RNA Levels

ING116070 Study
Dolutegravir + ABC-3TC and Impact on CNS HIV RNA Levels
ING116070 Study: Design

**Study Design: ING116070**

- **Background**: Single arm, phase 3b, open-label, multi-center trial to evaluate the distribution and antiviral activity of dolutegravir + abacavir-lamivudine in CSF

- **Inclusion Criteria (n = 13)**
  - Antiretroviral-naïve patients
  - Age $\geq 18$
  - HIV RNA $\geq 5,000$ copies/ml
  - CD4 count $\geq 200$ cells/mm$^3$
  - No active CDC AIDS condition (except KS)

- **Treatment Arm (n =12)**
  - Dolutegravir (QD) + Abacavir-lamivudine

### CSF Findings in Patients on Dolutegravir + ABC-3TC

<table>
<thead>
<tr>
<th>CSF Parameter</th>
<th>Week 2</th>
<th>Week 16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean CSF DTG Concentration total, ng/mL</td>
<td>16.2</td>
<td>12.6</td>
</tr>
<tr>
<td>CSF/Total Plasma Ratio for DTG Concentration</td>
<td>0.47</td>
<td>0.55</td>
</tr>
<tr>
<td>CSF HIV-1 RNA &lt; 50 copies/ml</td>
<td>11/12 (92%)</td>
<td>11/11 (100%)</td>
</tr>
<tr>
<td>CSF HIV-1 RNA &lt; 2 copies/ml</td>
<td>ND</td>
<td>11/12 (92%)</td>
</tr>
</tbody>
</table>

Conclusions: “The dolutegravir concentrations in CSF were similar to unbound plasma concentrations and exceeded the in vitro 50% inhibitory concentration for wild-type HIV (0.2 ng/mL), suggesting that dolutegravir achieves therapeutic concentrations in the central nervous system. The HIV-1 RNA reductions were similar in CSF and plasma.”

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