Switch from Enfuvirtide to Raltegravir with Multidrug-Resistant HIV

EASIER ANRS 138 Trial
### Study Design: EASIER ANRS 138

**Background:** Open label, randomized trial evaluating switching from enfuvirtide-based therapy to raltegravir-based therapy, in virologically suppressed patients with multidrug resistant HIV-1 infection.

**Inclusion Criteria (n = 170)**
- Age ≥18 years
- HIV RNA <400 copies/mL for >3 months
- History of triple class failure (PI, NRTI, NNRTI)
- Integrase inhibitor naïve

**Treatment Arms**
- Raltegravir 400 mg BID + background regimen
- Enfuvirtide + background regimen x 24 weeks, then switch enfuvirtide to raltegravir 400 mg BID

### Immediate Switch Arm
- **Raltegravir 400 mg BID + Background Regimen**
  - (n = 84)

### Delayed Switch Arm
- **Enfuvirtide x 24 weeks, then Raltegravir 400 mg BID + Background Regimen**
  - (n = 84)

Switch from Enfuvirtide to Raltegravir in Multidrug-Resistant HIV EASIER ANRS 138: Results

Virologic Response (Intent-to-Treat Analysis, censoring missing data)

Conclusions: “In well-suppressed patients with multidrug-resistant HIV infection, a switch from enfuvirtide to raltegravir is generally well tolerated and has sustained antiviral efficacy when combined with a potent background regimen.”

Switch from Enfuvirtide to Raltegravir in Multidrug-Resistant HIV

EASIER ANRS 138: Incidence of ALT Elevations

Week 24: ALT Elevation

Switch from Enfuvirtide to Raltegravir in Multidrug-Resistant HIV

EASIER ANRS 138: Risk Factors for ALT Elevation

<table>
<thead>
<tr>
<th>RISK FACTORS</th>
<th>Odds Ratio</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of boosted tipranavir</td>
<td>3.66</td>
<td>0.022</td>
</tr>
<tr>
<td>ALT elevation (≥ Grade 1)</td>
<td>10.3</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Alcohol use (&gt; 2 times/week)</td>
<td>0.39</td>
<td>0.281</td>
</tr>
<tr>
<td>Liver disease (steatosis/cirrhosis)</td>
<td>0.89</td>
<td>0.899</td>
</tr>
</tbody>
</table>

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.