Switch from Enfuvirtide to Raltegravir with Multidrug-Resistant HIV

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

EASIER ANRS 138: Study Design

**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
  - 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)

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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.”
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EASIER ANRS 138: Incidence of ALT Elevations

Week 24: ALT Elevation

## Multivariate Analysis of Baseline Risk Factors for ALT Elevation (≥ Grade 2)

<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>
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</tbody>
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