Intensive Enfuvirtide-Containing Antiretroviral Therapy

APOLLO (ANRS 130)
Study Design: APOLLO (ANRS 130)

- **Background:** Randomized, open label phase 3 study evaluating whether the addition of enfuvirtide to standard triple antiretroviral therapy improves immunological response in antiretroviral-naïve subjects with advanced HIV disease.

- **Inclusion Criteria (n = 195)**
  - Antiretroviral-naïve patients
  - Asymptomatic with CD4 count <100 cells/mm³ or stage B/C disease with CD4 count <200 cells/mm³
  - Any HIV RNA level

- **Treatment Arms**
  - LPV-RTV 400/100 mg BID or EFV 600 mg QD, + TDF-FTC + Enfuvirtide 90 mg BID
  - LPV-RTV 400/100 mg BID or EFV 600 mg QD, + TDF-FTC

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**Enfuvirtide arm**
LPV/r or EFV + TDF-FTC + Enfuvirtide
(n = 101)

**Control arm**
LPV/r or EFV + TDF-FTC
(n = 94)

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Result

Weeks 12 through 48: Virologic Response

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Result

Week 24: Immunologic Response

Intensive Enfuvirtide-containing Antiretroviral Therapy
APOLLO (ANRS 130): Result

Week 24: Immunologic Response

### Clinical adverse events in Either Arm

<table>
<thead>
<tr>
<th>Clinical adverse events</th>
<th>Enfuvirtide + Standard ART arm (n = 100)</th>
<th>Standard ART (n= 94)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any grade</td>
<td>92%</td>
<td>90%</td>
</tr>
<tr>
<td>Any grade and treatment related</td>
<td>61%</td>
<td>55%</td>
</tr>
<tr>
<td>Grades 3 and 4</td>
<td>23%</td>
<td>30%</td>
</tr>
<tr>
<td>Grades 3 and 4 and treatment related</td>
<td>7%</td>
<td>9%</td>
</tr>
<tr>
<td>Serious</td>
<td>28%</td>
<td>29%</td>
</tr>
<tr>
<td>Serious and study treatment related</td>
<td>9%</td>
<td>14%</td>
</tr>
<tr>
<td>AIDS events</td>
<td>20%</td>
<td>13%</td>
</tr>
<tr>
<td>IRIS</td>
<td>15%</td>
<td>21%</td>
</tr>
<tr>
<td>Deaths</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Conclusions: “Although inducing a more rapid virological response, addition of enfuvirtide to a standard cART does not improve the immunological outcome in naive HIV-infected patients with severe immunosuppression.”

The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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