Lopinavir-RTV + TDF-FTC versus Maraviroc + TDF-FTC for PEP

MARAVI-PEP Trial
Lopinavir-RTV + TDF-FTC versus Maraviroc + TDF-FTC for PEP
MARAVI-PEP: Study Design

Study Design: MARAVI-PEP

- **Background**: Prospective, randomized, open-label, phase 4 trial comparing lopinavir-ritonavir versus maraviroc, both with tenofovir-emtricitabine, for HIV postexposure prophylaxis (PEP)

- **Inclusion Criteria** (n=237)*
  - Age ≥18
  - Residents of Barcelona
  - Presented to ER due to potential HIV sexual exposure
  - Met criteria for PEP per Spanish guidelines

- **Treatment Arms**
  - Lopinavir-ritonavir 400-100 mg BID + TDF-FTC
  - Maraviroc 300 mg BID + TDF-FTC

*Only 187 individuals who were randomized attended first scheduled visit

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MARAVI-PEP: Result

Day 28: PEP Non-completion

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MARAVI-PEP: Result (subgroup analysis)

Day 28: PEP Non-completion (for patients attending day 1 visit – ITT)

Lopinavir-RTV + TDF-FTC versus Maraviroc + TDF-FTC for PEP MARAVI-PEP: Result

Adverse Events (reported by patients attending day 1 visit)

**Factors Associated with PEP Non-completion at Day 28 (univariate analysis)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PEP discontinuations due to any cause in entire cohort, OR (95% CI) (n = 237)</th>
<th>PEP discontinuations due to any cause in patients attending day 1 visit, OR (95% CI) (n = 182)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomization arm: Lopinavir-RTV</td>
<td>1.3</td>
<td>2.9</td>
</tr>
<tr>
<td>Race: non-Caucasian</td>
<td>2.1</td>
<td>2.2</td>
</tr>
<tr>
<td>Risk assessment: low</td>
<td>1.2</td>
<td>4.8</td>
</tr>
<tr>
<td>Previous PEP: yes</td>
<td>2.4</td>
<td>1.6</td>
</tr>
<tr>
<td>Presence of adverse events due to PEP*</td>
<td>N/A</td>
<td>0.3</td>
</tr>
</tbody>
</table>

*Only measured in patients who attended day 1 visit

Conclusions: “PEP non-completion and adverse events were both significantly higher in patients allocated to ritonavir-boosted lopinavir. These data suggest that maraviroc is a well-tolerated antiretroviral that can be used in this setting.”

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