EVG-COBI-TDF-FTC versus ATV + RTV + TDF-FTC in Women

WAVES Study
**Study Design: WAVES**

- **Background:** Randomized, double-blind, phase 3 trial comparing elvitegravir-cobicistat-tenofovir-emtricitabine with atazanavir + ritonavir + tenofovir DF-emtricitabine in women

- **Inclusion Criteria (n = 575)**
  - Antiretroviral-naïve women
  - Age ≥ 18
  - HIV RNA ≥ 500 copies/ml
  - Any CD4 count

- **Treatment Arms**
  - Elvitegravir-Cobicistat-TDF-FTC
  - Atazanavir + Ritonavir + TDF-FTC

EVG-COBI-TDF-FTC versus ATV + RTV + TDF-FTC (in Women)

WAVES Study: Result

Week 48 Virologic Response: Snapshot Analysis (ITT, Missing=Failure)

EVG-COBI-TDF-FTC versus ATV + RTV + TDF-FTC (in Women) WAVES Study: Result

Week 48 Virologic Response: Snapshot Analysis (ITT, Missing=Failure)

### EVG-COBI-TDF-FTC versus ATV + RTV + TDF-FTC (in Women)

**WAVES Study: Common Adverse Events**

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Events in ≥ 10% of Subjects in Either Group</th>
<th>EVG-COBI-TDF-FTC (n = 289)</th>
<th>ATV + RTV + TDF-FTC (n= 286)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>16%</td>
<td>15%</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>16%</td>
<td>15%</td>
</tr>
<tr>
<td>Malaria</td>
<td>11%</td>
<td>8%</td>
</tr>
<tr>
<td>Nausea</td>
<td>15%</td>
<td>14%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10%</td>
<td>6%</td>
</tr>
<tr>
<td>Jaundice</td>
<td>&lt;1%</td>
<td>11%</td>
</tr>
<tr>
<td>Icterus</td>
<td>&lt;1%</td>
<td>12%</td>
</tr>
</tbody>
</table>

**Interpretation:** “WAVES shows that clinical trials of ART regimens in global and diverse populations of treatment-naive women are possible. The findings support guidelines recommending integrase inhibitor based regimens in first-line antiretroviral therapy.”
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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