Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment

Study 112
Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Design

**Background**: Open-label, single-arm, phase 3 trial evaluating switching to once-daily elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine from baseline ART*

**Inclusion Criteria** (n = 242)
- HIV RNA < 50 copies/mL for ≥6 months
- eGFR stable at 30-69 mL/min ≥3 months
- CD4 ≥50 cells/mm3
- No new AIDS conditions in past 30 days
- No resistance to EVG, FTC, or TDF

**Treatment Arms**
- Switch to EVG-COBI-TAF-FTC

*Baseline ART*

NRTIs: Tenofovir DF 65%, Abacavir 22%, Other NRTI 7%, No NRTI 5%

Third Agent: PI 44%, NNRTI 42%, INSTI 24%, CCR5 Antagonist 3%

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment
Study 112: Result

Week 48 Virologic Response

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Subgroup Analysis Result

Change in Estimated GFR* from Baseline to Weeks 24 and 48

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment
Study 112: Result

Week 48: Changes in General Proteinuria

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Result

Week 48: Changes in Tubular Proteinuria

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment
Study 112: Result

Week 48: Changes in Bone Mineral Density (BMD)

<table>
<thead>
<tr>
<th></th>
<th>Mean Change in BMD (%)</th>
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<tbody>
<tr>
<td>Hip</td>
<td>1.47</td>
</tr>
<tr>
<td>Spine</td>
<td>2.29</td>
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</tbody>
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Week 48: Changes in Spine and Hip Bone Mineral Density (BMD)

Spine
- ≥3% gain: 4%
- Gain or loss <3%: 37%
- Loss ≥3%: 59%

Hip
- ≥3% gain: 6%
- Gain or loss <3%: 72%
- Loss ≥3%: 22%

Interpretation: “Switch to E/C/F/TAF was associated with minimal change in GFR. Proteinuria, albuminuria and bone mineral density significantly improved. These data support the efficacy and safety of once daily E/C/F/TAF in HIV+ patients with mild or moderate renal impairment without dose adjustment.”
The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents 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. For more information, please visit HRSA.gov. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.