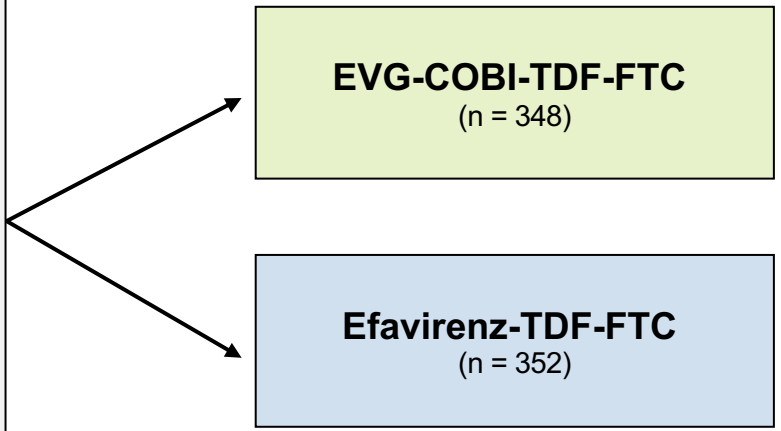
Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC

Study 102

Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC Study 102: Design

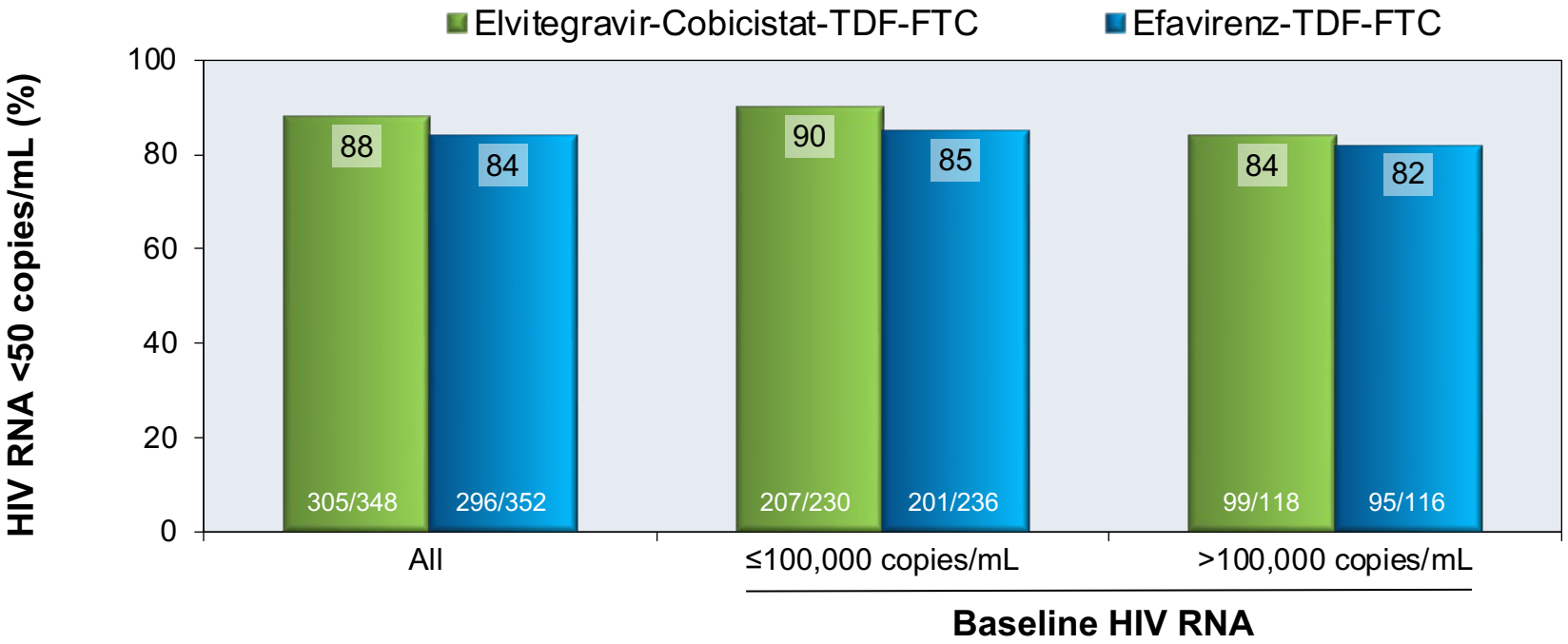
- **Background**: Randomized, double-blind, phase 3 trial comparing elvitegravir-cobicistat-tenofovir DF-emtricitabine with efavirenz-tenofovir DF-emtricitabine
- **Inclusion Criteria (n = 700)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥5,000 copies/mL
  - No AIDS conditions in previous 30 days
- **Treatment Arms**
  - Elvitegravir-Cobicistat-TDF-FTC
  - Efavirenz-TDF-FTC



Source: Sax PE, et al. Lancet. 2012;379:2439-48.

Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC Study 102: Results

Week 48 Virologic Response



Source: Sax PE, et al. Lancet. 2012;379:2439-48.

Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC Study 102: Common Adverse Events

Treatment-Emergent Adverse Events in ≥ 10% of Subjects in Either Group	EVG-COBI-TDF-FTC (n = 348)	EFV-TDF-FTC (n= 352)
Diarrhea	23%	19%
Nausea*	21%	14%
Fatigue	11%	13%
Upper Respiratory Tract Infection	14%	11%
Dizziness^	7%	24%
Headache	14%	10%
Abnormal Dreams^	15%	27%
Insomnia†	9%	14%
Depression	9%	11%
Rash §	6%	12%

*p < 0.016; ^p < 0.001; †p < 0.031; § p = 0.009

Source: Sax PE, et al. Lancet. 2012;379:2439-48.

Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC Study 102: Conclusions

Interpretation: “This study met the primary endpoint of non-inferiority of elvitegravir/cobicistat/emtricitabine/tenofovir (EVG/COBI/TDF/FTC) to efavirenz/emtricitabine/tenofovir (EFV/TDF/FTC) and demonstrates the robust antiviral efficacy of the only integrase inhibitor-based single tablet regimen for initial HIV treatment, irrespective of viral load.”

Source: Sax PE, et al. Lancet. 2012;379:2439-48.

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