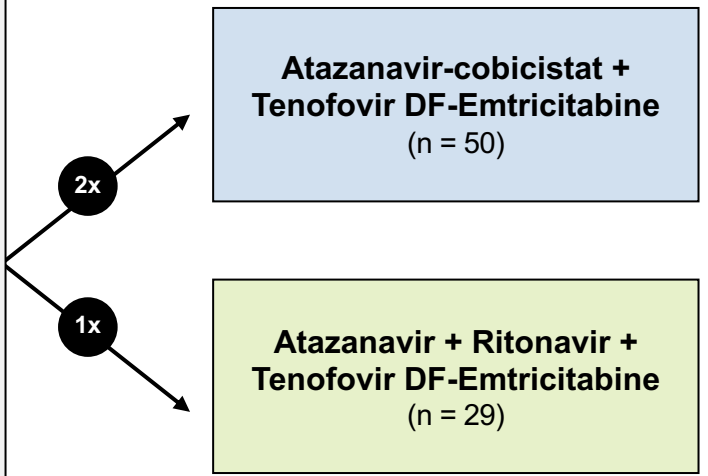
Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 2)

Study 105

National HIV Curriculum

Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 2) Study 105: Study Design

- **Background**: Randomized, partially placebo-controlled, double-blind phase 2 trial to compare the safety and efficacy of cobicistat and ritonavir as pharmacokinetic enhancers administered with atazanavir and fixed-dose tenofovir DF-emtricitabine in treatment-naïve adults with HIV infection
- **Inclusion Criteria** (n = 85)
  - Age ≥18 years
  - Antiretroviral treatment-naïve
  - HIV RNA ≥5000 copies/mL
  - CD4 count >50 cells/mm^3
- **Treatment Arms (all once daily)**
  - Atazanavir-cobicistat (300/150 mg) + TDF-FTC
  - Atazanavir 300 mg + Ritonavir 100 mg + TDF-FTC



Source: Elion R, et al. AIDS. 2011;25:1881-6.

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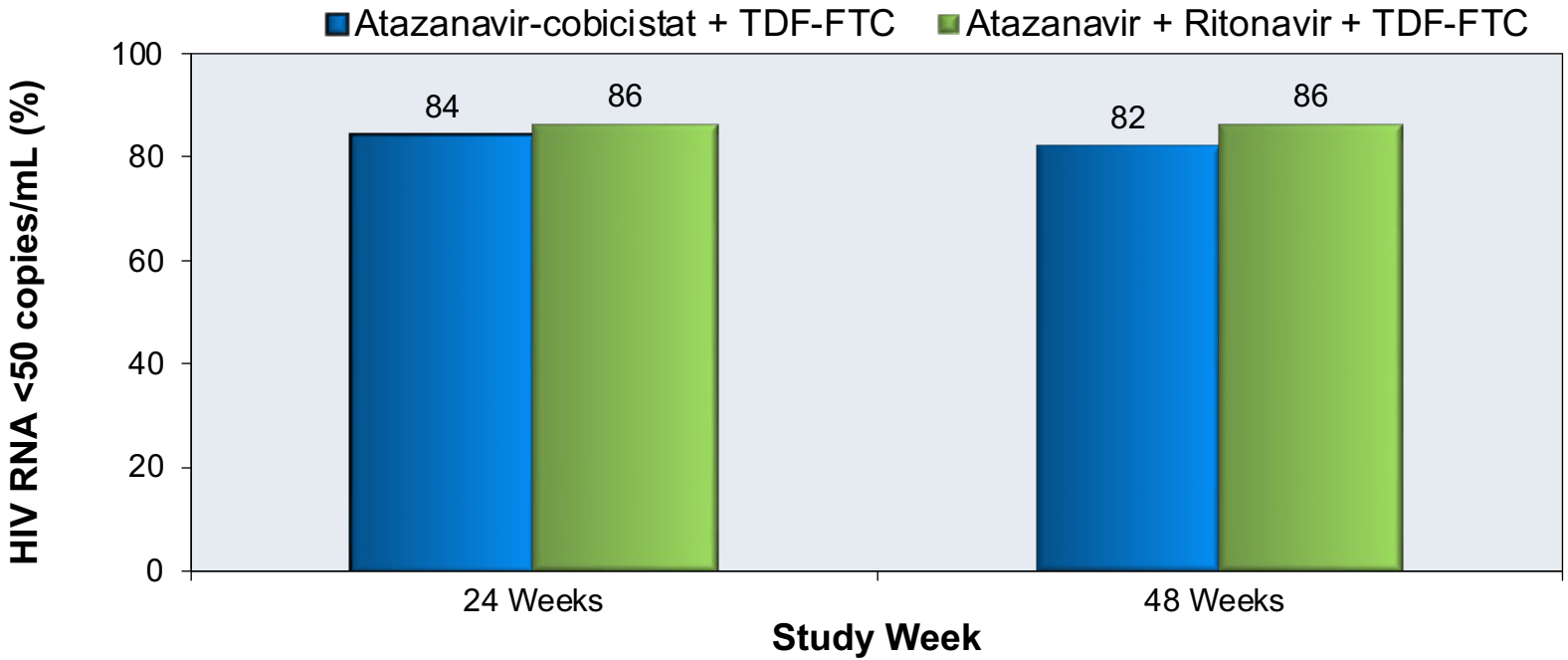
Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 2) Study 105: Results

Week 24 and 48: Virologic Response (ITT, Missing=Failure)



Source: Elion R, et al. AIDS. 2011;25:1881-6.

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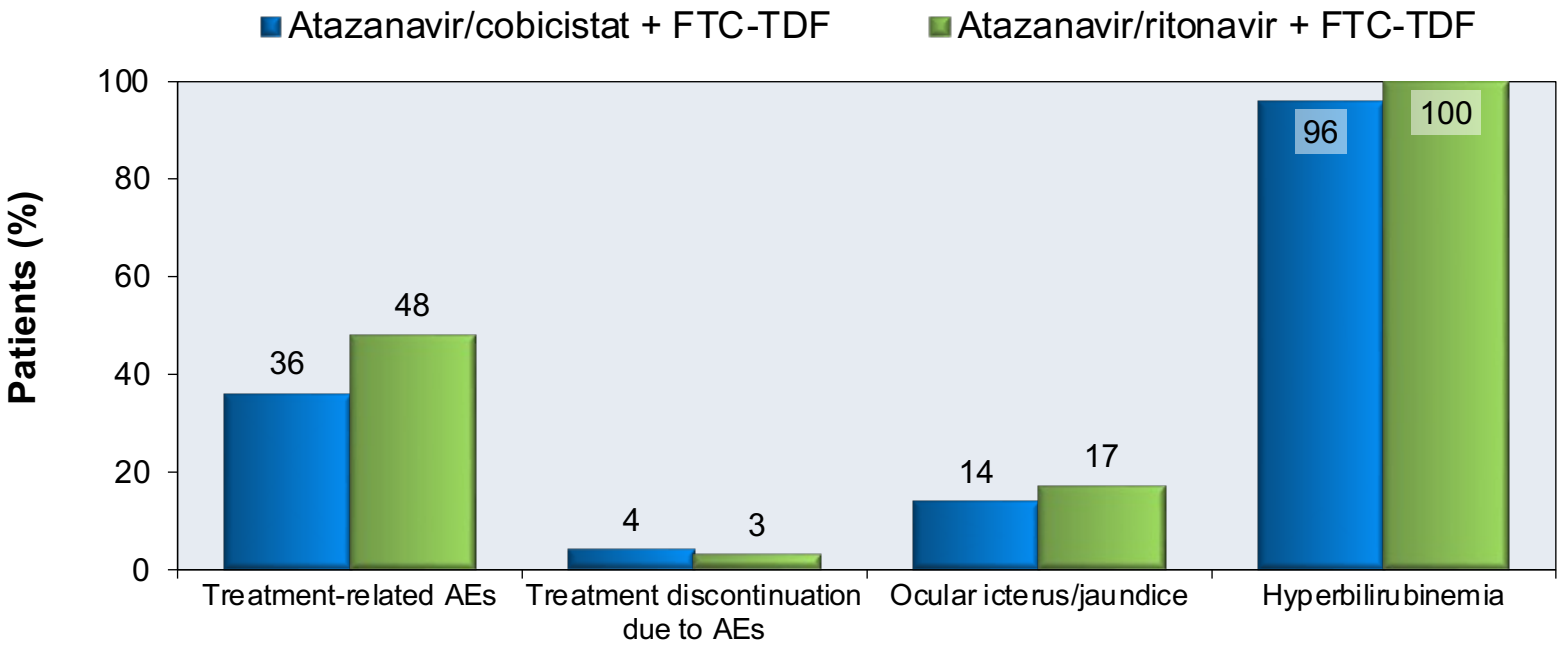
Adverse Events and Treatment Discontinuations



Source: Elion R, et al. AIDS. 2011;25:1881-6.

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Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 2) Study 105: Conclusions

Conclusion: “Using cobicistat and ritonavir as pharmacoenhancers for atazanavir and administered with emtricitabine/tenofovir DF achieved comparable rates of virologic suppression and CD4 cell count increase with satisfactory safety profiles.”

Source: Elion R, et al. AIDS. 2011;25:1881-6.

Acknowledgments

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AETC AIDS Education & Training Center Program

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