

Intensive Enfuvirtide-containing Antiretroviral Therapy
A5173 Study

Intensive Enfuvirtide-containing Antiretroviral Therapy

A5173: Study Design

Study Design: A5173

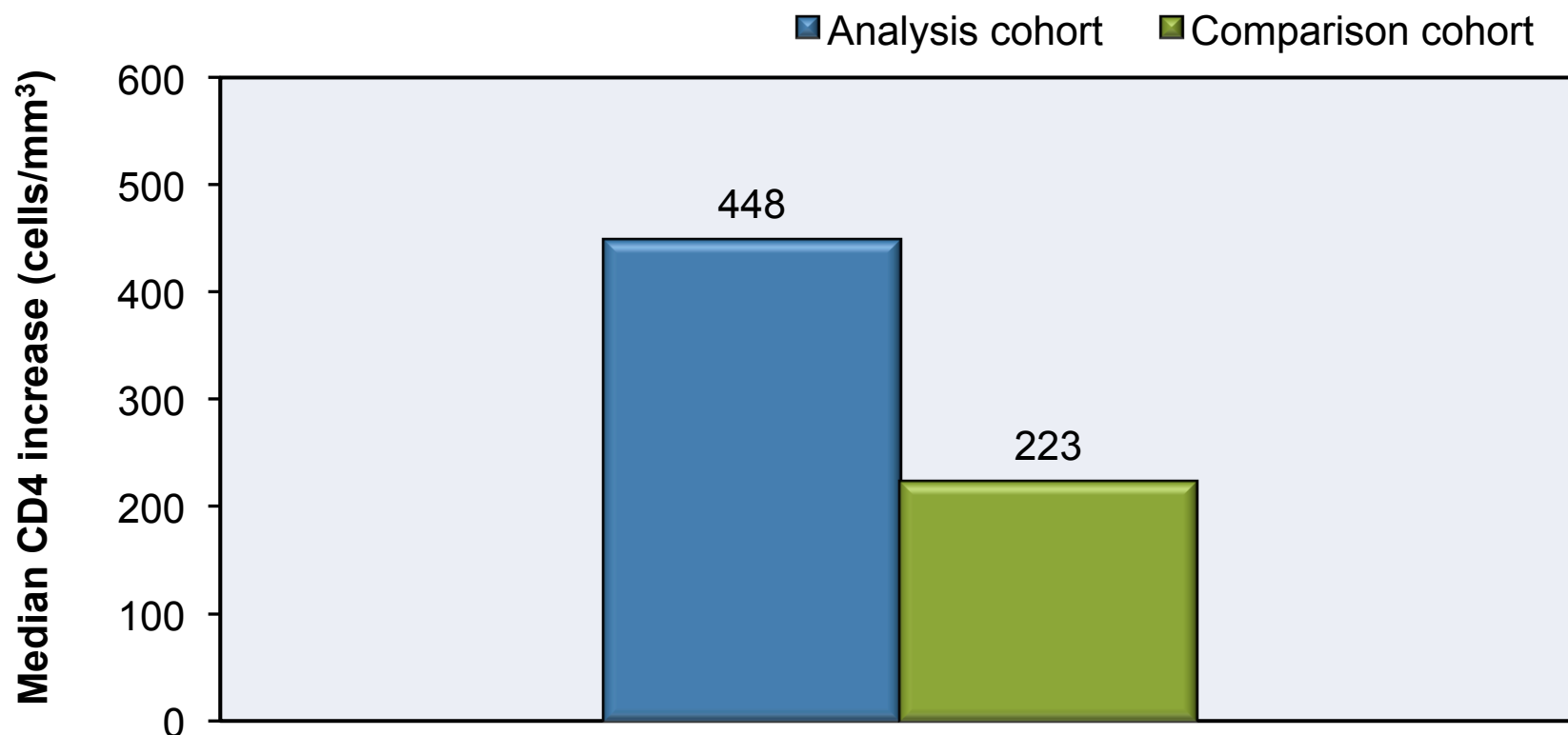
- **Background:** Single-arm, pilot study to evaluate whether intensive enfuvirtide-containing antiretroviral therapy leads to a decay in the latent reservoir of HIV-infected resting memory CD4 cells.
- **Inclusion Criteria (n = 19)**
 - Antiretroviral-naïve patients
 - CD4 ≥ 100 cells/mm³
 - HIV RNA $\geq 1,000$ copies/mL
 - No drug resistance mutations by genotype
- **Treatment Arms**
 - ENF 90 mg BID + TDF 300 mg QD + (FTC 200 mg QD or 3TC 300 mg QD) + SQV 1000 mg BID + RTV 100 mg BID

**Enfuvirtide +
TDF + (FTC or 3TC) +
Ritonavir + Saquinavir**
(n = 19)

Intensive Enfuvirtide-containing Antiretroviral Therapy

A5173: Result

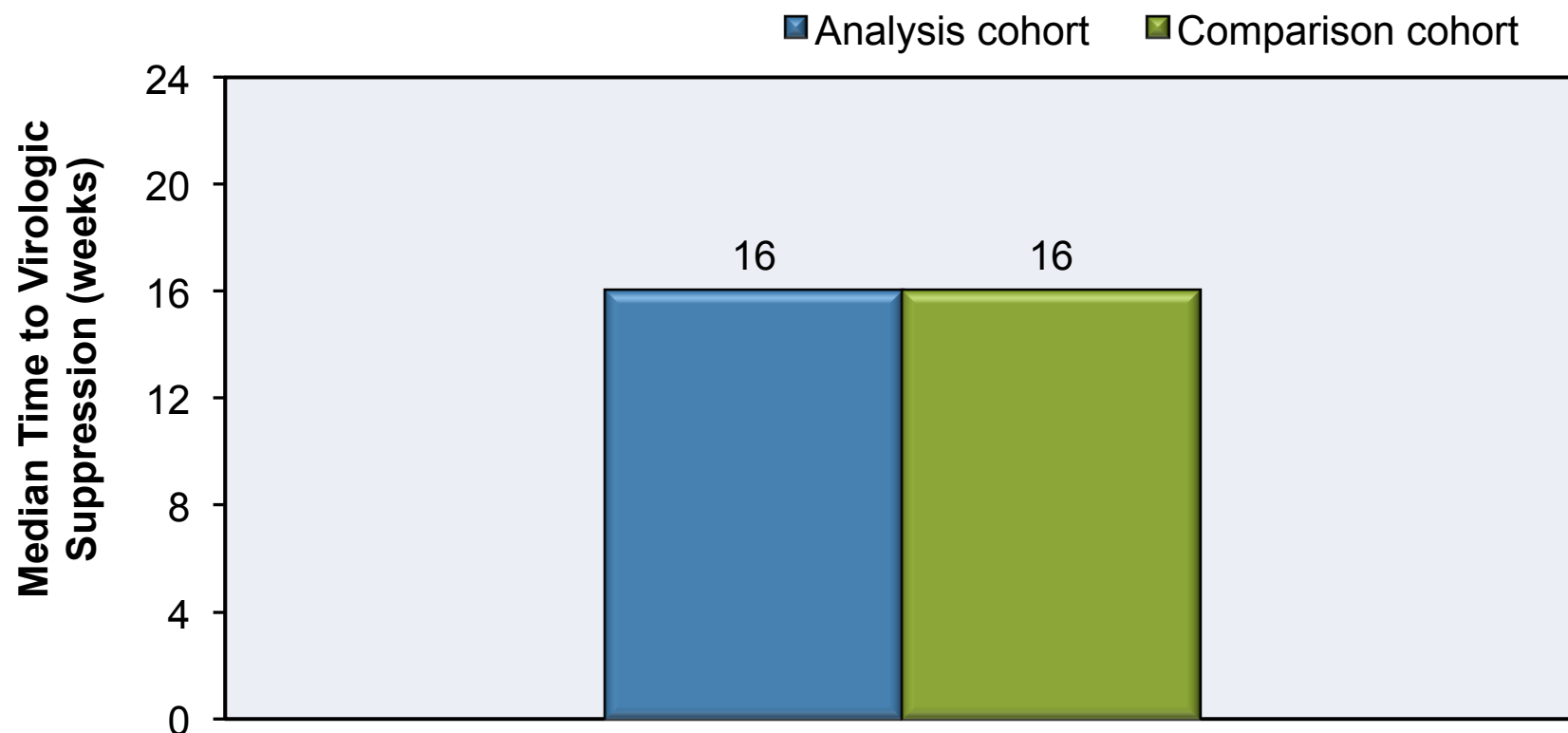
Week 48: Immunologic Response



Analysis Cohort = 9 patients who remained on ENF through 48 weeks and achieved HIV RNA <50 copies/mL.
Comparison Cohort = 6 patients who had HIV RNA < 50 copies/mL but stopped ENF before 48 weeks.

Intensive Enfuvirtide-containing Antiretroviral Therapy A5173: Result

Week 48: Virologic Response



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Comparison Cohort = 6 patients who had HIV RNA < 50 copies/mL but stopped ENF before 48 weeks.

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A5173: Result (Latent Reservoir Decay)

- Analysis Cohort consisted of 9 patients who had virologic suppression and continued enfuvirtide-containing ART for at least 48 weeks.
- Patients in the Analysis Cohort had a median of 4 latent-reservoir measurements each.
 - 4/9 patients had a slight decrease of the number of latently infected cells
 - 5/9 patients had a slight increase in the number of latently infected cells
- No evidence for decay of the latent reservoir in Analysis Cohort

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A5173: Conclusions

Conclusions: “In enfuvirtide-treated patients with virological suppression, there was no decay of the latent reservoir (95% confidence interval for half-life, 11 months to infinity). The stability of the latent reservoir despite intensive therapy suggests that new strategies are needed to eradicate HIV-1 from this reservoir.”

Acknowledgment

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