Intensive Enfuvirtide-containing Antiretroviral Therapy

A5173 Study
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A5173: Study Design

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- **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 ≥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

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

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 (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

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.”
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