OBR + Enfuvirtide Intensification versus OBR Alone

INNOVE Study
INNOVE: Study Design

**Study Design: INNOVE**

- **Background**: Prospective, randomized, open-label trial evaluating the efficacy of short-course enfuvirtide intensification with optimized background regimen (OBR) compared with OBR alone in antiretroviral-experienced patients with HIV infection and multi-drug-resistant virus.

- **Inclusion Criteria (n = 29)**
  - Age ≥ 18 years of age
  - Virologic failure on same ART x 4 weeks with HIV RNA > 1000 copies/mL
  - Naïve to enfuvirtide and susceptible to ≥2 active medications (genotype sensitivity score ≥2)

- **Treatment Arms**
  - OBR + Enfuvirtide 90mg SC BID
  - OBR alone

INNOVE = INduction of a New Optimized treatment in patients with Virologic failure using Enfuvirtide

OBR + Enfuvirtide Intensification versus OBR Alone
INNOVE: Results

Week 24: Virologic Response (Intent-to-Treat)

*Primary endpoint = Proportion of patients with HIV RNA <50 copies/ml at Week 24 and treated by Enfuvirtide for 14 weeks in the OBR + ENF group

Conclusions: “A 3-month short-course intensified treatment with ENF did not improve Week-24 virological response in treatment-experienced patients infected with HIV-1 harboring resistant viruses that were still susceptible to two antiretroviral drugs.”

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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