OBR + Enfuvirtide Intensification versus OBR Alone INNOVE Study



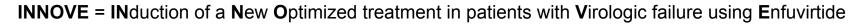
OBR + Enfuvirtide Intensification versus OBR Alone INNOVE: Study Design

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 \geq 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



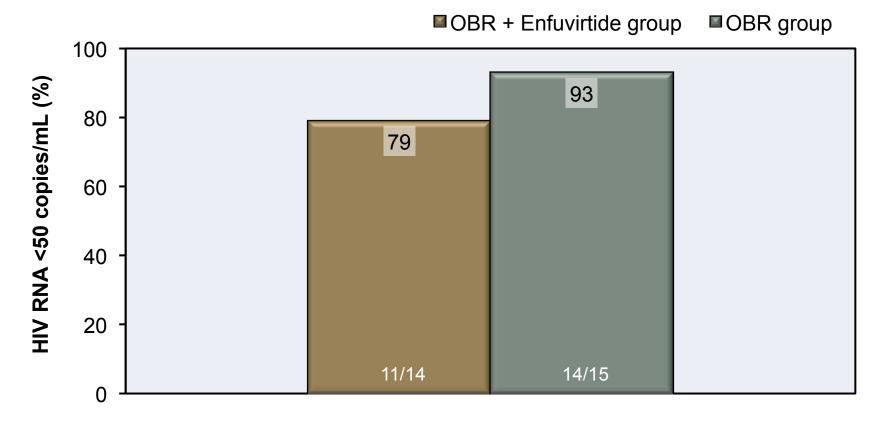
OBR + Enfuvirtide Group (n = 14) OBR Group (n =15)

Source: Morand-Joubert L, et al. J Med Virol. 2012;84:1710-8.



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

Source: Morand-Joubert L, et al. J Med Virol. 2012;84:1710-8.



OBR + Enfuvirtide Intensification versus OBR Alone INNOVE: Conclusions

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."

Source: Morand-Joubert L, et al. J Med Virol. 2012;84:1710-8.



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