

Lopinavir/Ritonavir (Kaletra®)

Abbott Protocol M03-613: A Randomized Open-Label Study Assessing Safety, Tolerability, Efficacy, and Metabolic Effects of a Simplified Lopinavir/Ritonavir-Based Induction/Maintenance Therapy in Antiretroviral-Naïve HIV-Infected Subjects.

Purpose: To assess the safety, tolerability, and antiviral activity of the following treatment strategies:

PI Induction Maintenance:

- Induction therapy with lopinavir/ritonavir (Kaletra®) BID + Combivir® [lamivudine (3TC), zidovudine (AZT)] BID followed by maintenance therapy with lopinavir/ritonavir (Kaletra®) BID monotherapy.

RTI only regimen:

- EFV (Sustiva®) QD + Combivir® BID

Assess the metabolic effects and morphologic changes associated with the treatment strategies.

About the study: 150 patients will be enrolled in the study at approximately 40 sites. Subjects will be randomized to either the PI induction/maintenance regimen or the RTI regimen in a 2:1 ratio as follows:

- Induction with lopinavir/ritonavir (Kaletra®) 400mg/100mg BID + 3TC/AZT 150 mg/300mg (Combivir®) BID followed by maintenance with lopinavir/ritonavir (Kaletra®) 400mg/100mg BID monotherapy (N=100)
- EFV (Sustiva®) 600mg QD + 3TC/AZT 150mg/300mg (Combivir®) BID (N=100)

Required:

- HIV positive with plasma HIV RNA > 1000 copies/ml
- At least 18 years old
- Antiretroviral naïve
- CD4+ (T-cells) range not applicable
- No evidence of acute infection
- No treatment for an active opportunistic infection within 30 days of initiating study drug
- Karnofsky Score >70

Study Location:

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