Raltegravir plus Ritonavir-Boosted Darunavir ACTG 5262 Trial



Raltegravir plus Ritonavir-Boosted Darunavir ACTG 5262: Study Design

Study Design: ACTG 5262

• **Background**: Open-label, single-arm, phase 2 study evaluating the efficacy of a NRTI-sparing regimen consisting of boosted darunavir plus raltegravir in persons with HIV.

• Inclusion Criteria (n = 112)

- Age ≥18 years
- Antiretroviral-naïve
- HIV RNA ≥5000 copies/mL
- More than one darunavir resistance-associated mutation (RAM) or known major integrase RAM

Treatment Arm

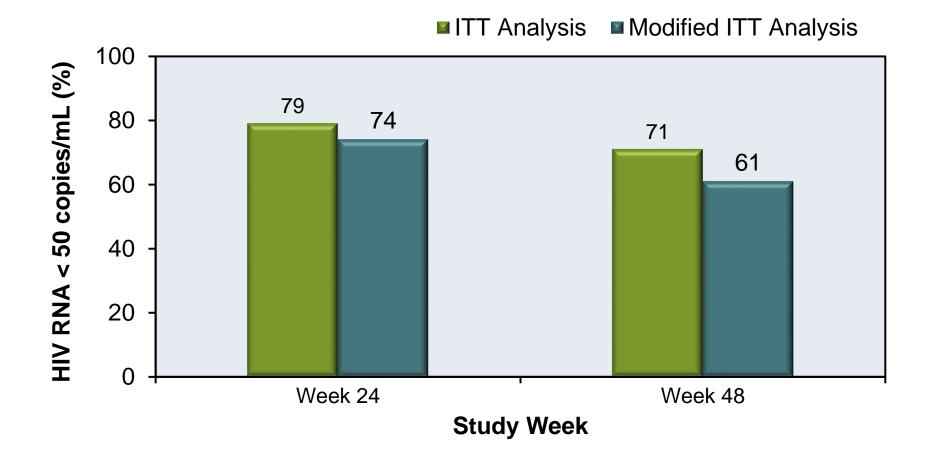
- Darunavir 800 mg + Ritonavir 100 mg QD + Raltegravir 400 mg BID Darunavir 800 mg QD + Ritonavir 100 mg QD + Raltegravir 400 mg BID (n = 112)



Source: Taiwo B, et al. AIDS. 2011;25:2113-22.

Raltegravir plus Ritonavir-Boosted Darunavir ACTG 5262 Trial: Result

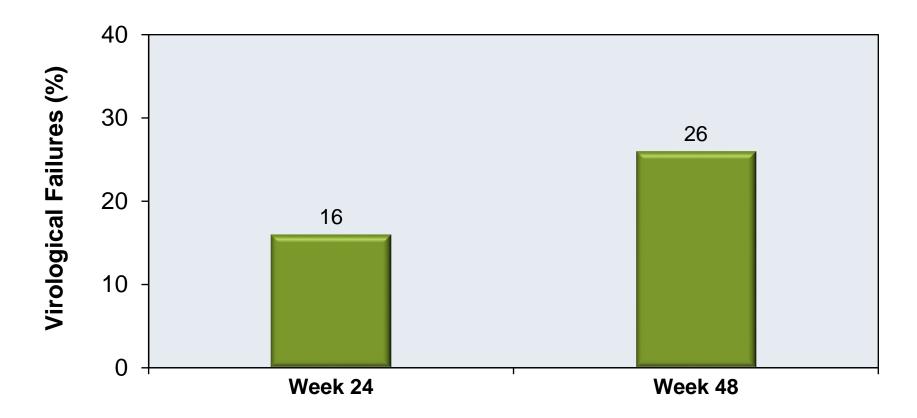
Week 24 and Week 48: Virologic Efficacy





Raltegravir plus Ritonavir-Boosted Darunavir ACTG 5262 Trial: Result

Week 24 and Week 48: Virologic Failure (Intent-to-Treat Analysis)



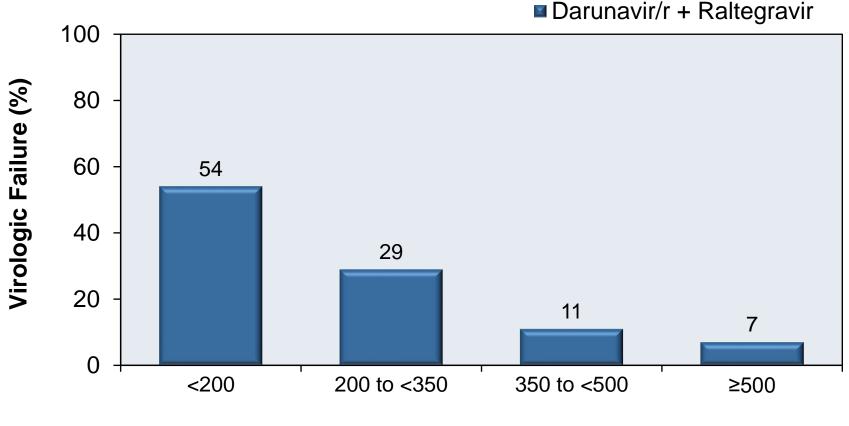
Virologic failure associated with baseline HIV RNA >100,000 copies/mL and lower CD4 count

Source: Taiwo B, et al. AIDS. 2011;25:2113-22.



Raltegravir plus Ritonavir-Boosted Darunavir ACTG 5262: Result

Virologic Failure, by Baseline CD4 Count



Baseline CD4 Count (cells/mm³)



Raltegravir plus Ritonavir-Boosted Darunavir ACTG 5262: Conclusions

Conclusion: "DRV/r + RAL was effective and well tolerated in most patients, but virological failure and integrase resistance were common, particularly in patients with baseline viral load more than 100,000 copies/ml."

Source: Taiwo B, et al. AIDS. 2011;25:2113-22.



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