

Raltegravir plus Ritonavir-Boosted Darunavir
NEAT001/ANRS 143 Trial

Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Study Design

Study Design: NEAT001/ANRS 143

- **Background:** Randomized, open-label, non-inferiority trial study to evaluate the efficacy and safety of a NtRTI-sparing regimen of raltegravir and boosted darunavir vs. combination tenofovir DF-emtricitabine and boosted darunavir.
- **Inclusion Criteria (n = 805)**
 - Age ≥ 18 years
 - Antiretroviral-naïve
 - HIV RNA $> 1,000$ copies/mL
 - CD4 < 500 cells/mm³
 - No major resistance mutations
- **Treatment Arms**
 - Darunavir 800 mg QD + Ritonavir 100 mg QD + Raltegravir 400 mg BID
 - Darunavir 800 mg QD + Ritonavir 100 mg QD + TDF-FTC QD

**Darunavir + Ritonavir QD
+ Raltegravir BID**

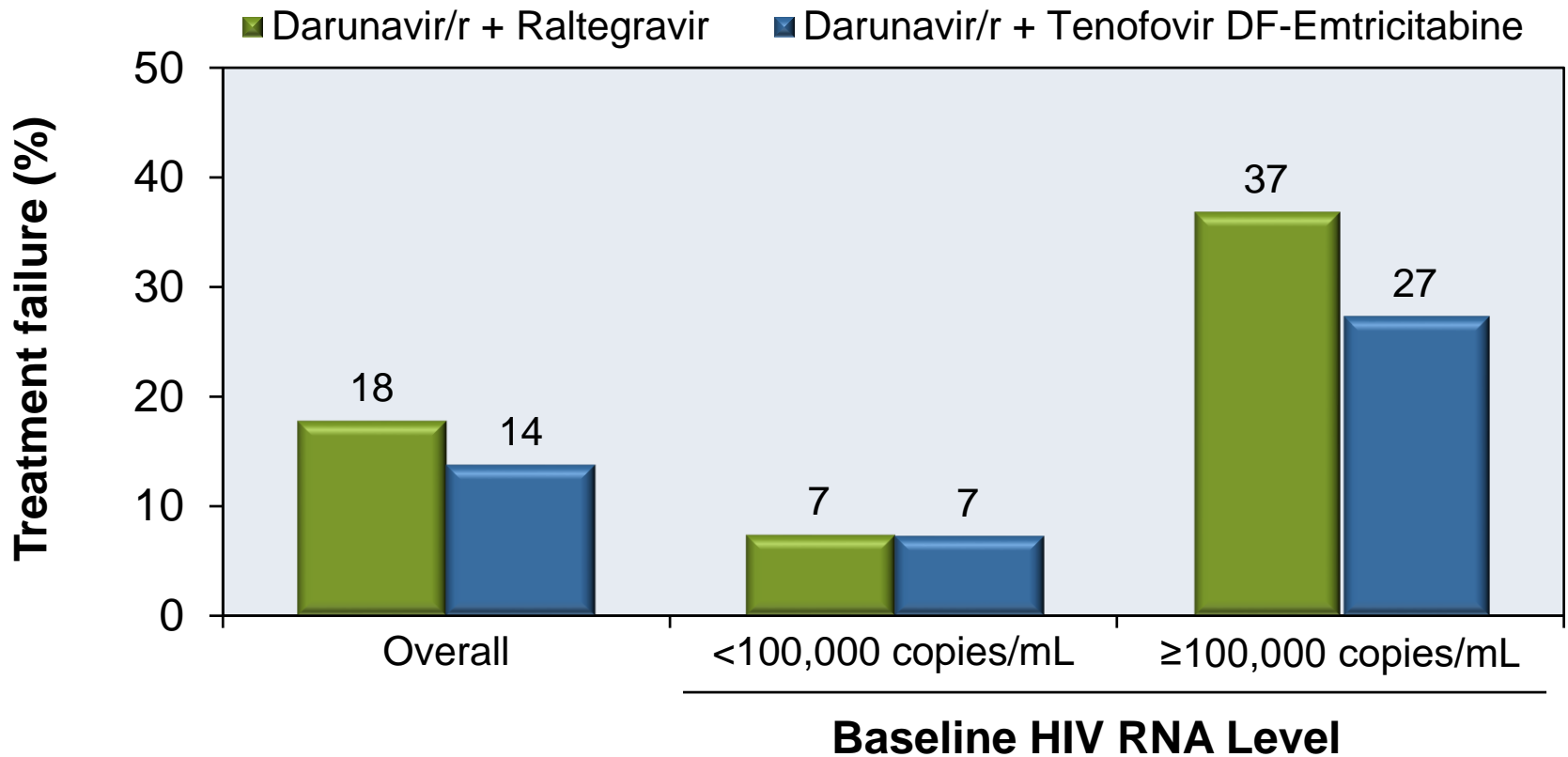
(n = 401)

**Darunavir + Ritonavir QD
+ TDF-FTC QD**

(n = 404)

Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

Week 96: Treatment Failure, by Baseline HIV RNA*

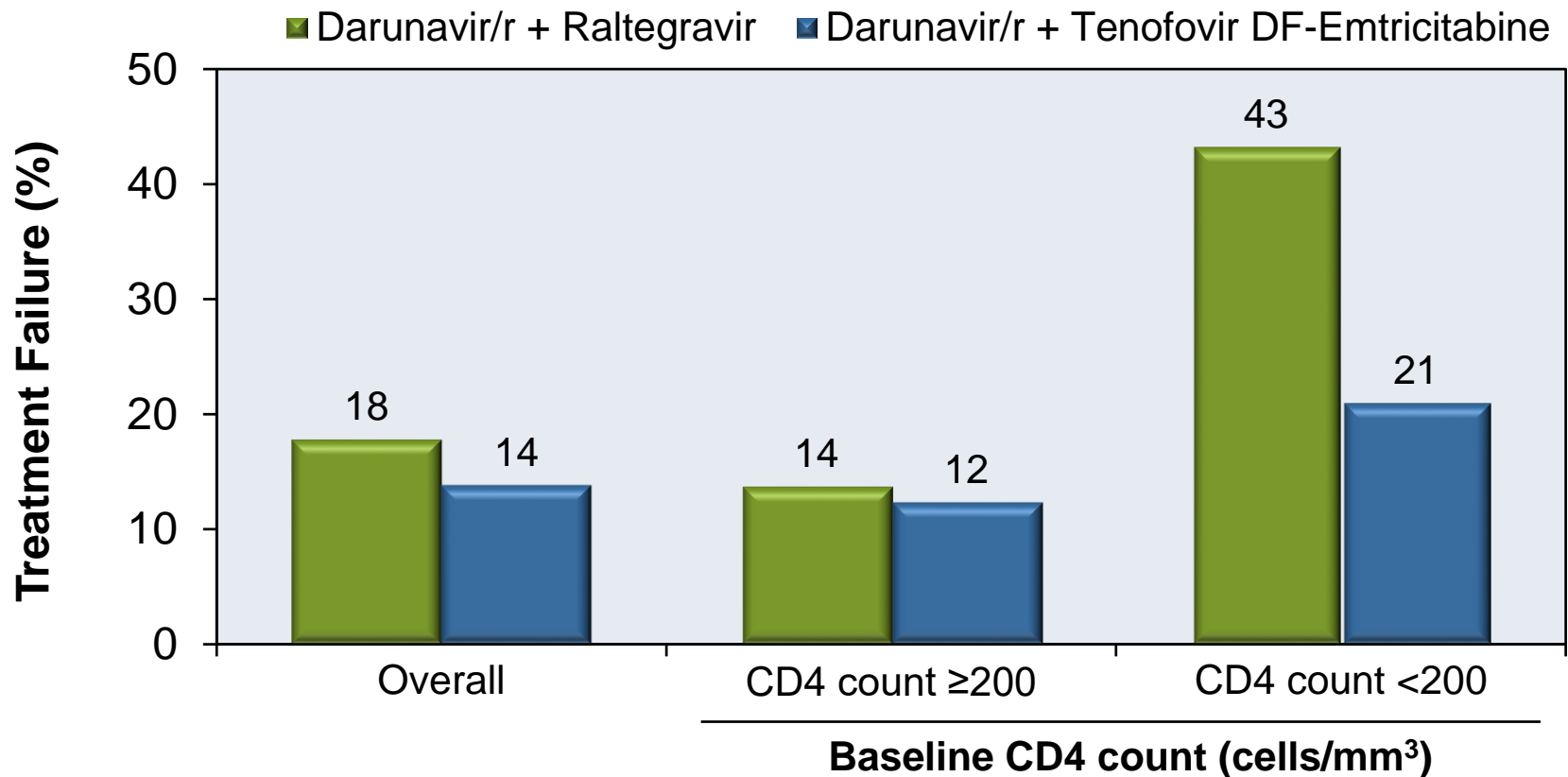


*Kaplan-Meier estimates of proportion of patients reaching endpoints)

Source: Raffi F, et al. Lancet. 2014;384:1942-51.

Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

Week 96: Treatment Failure, by Baseline CD4 Count*

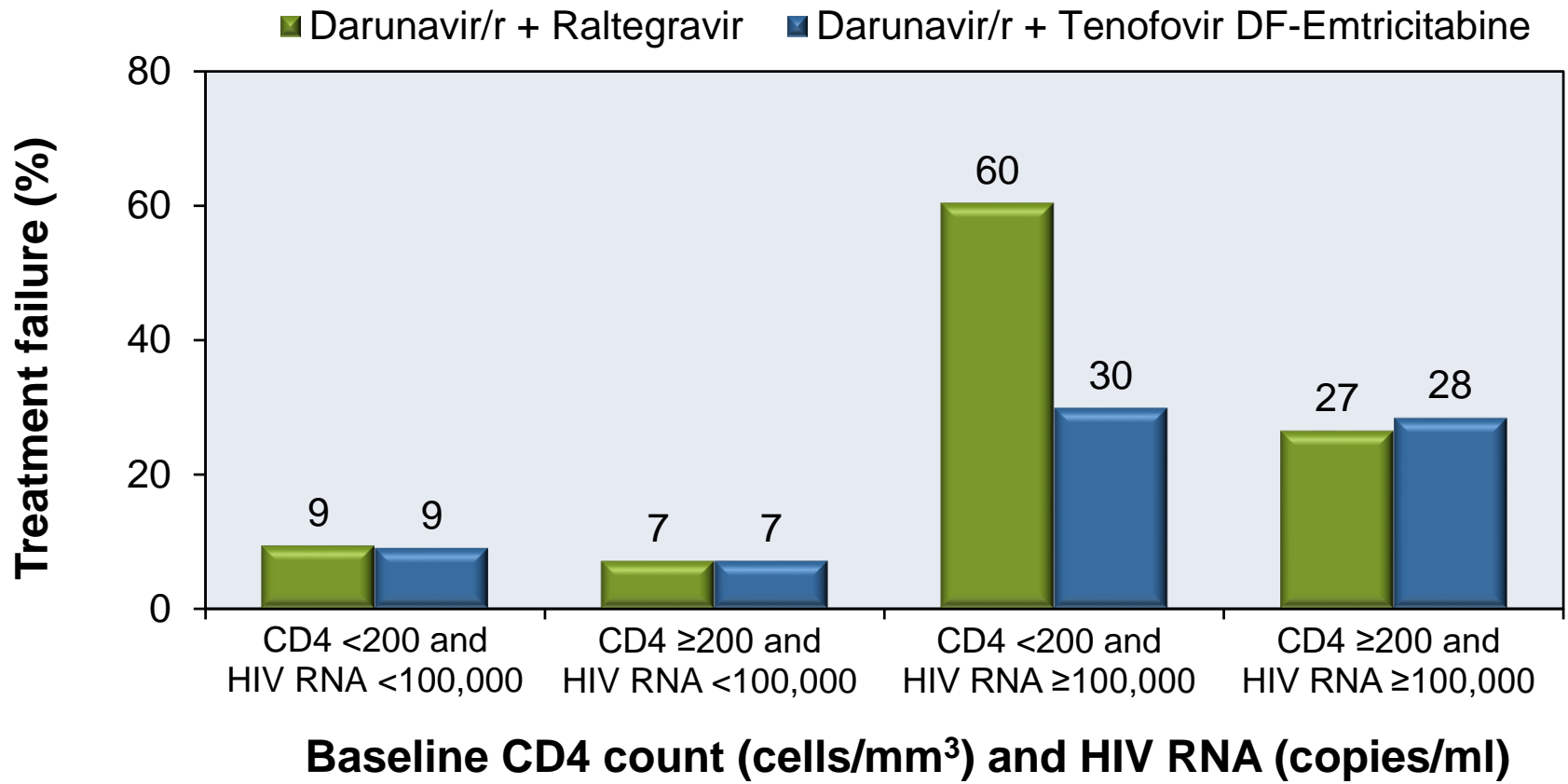


*Kaplan-Meier estimates of proportion of patients reaching endpoints)

Source: Raffi F, et al. Lancet. 2014;384:1942-51.

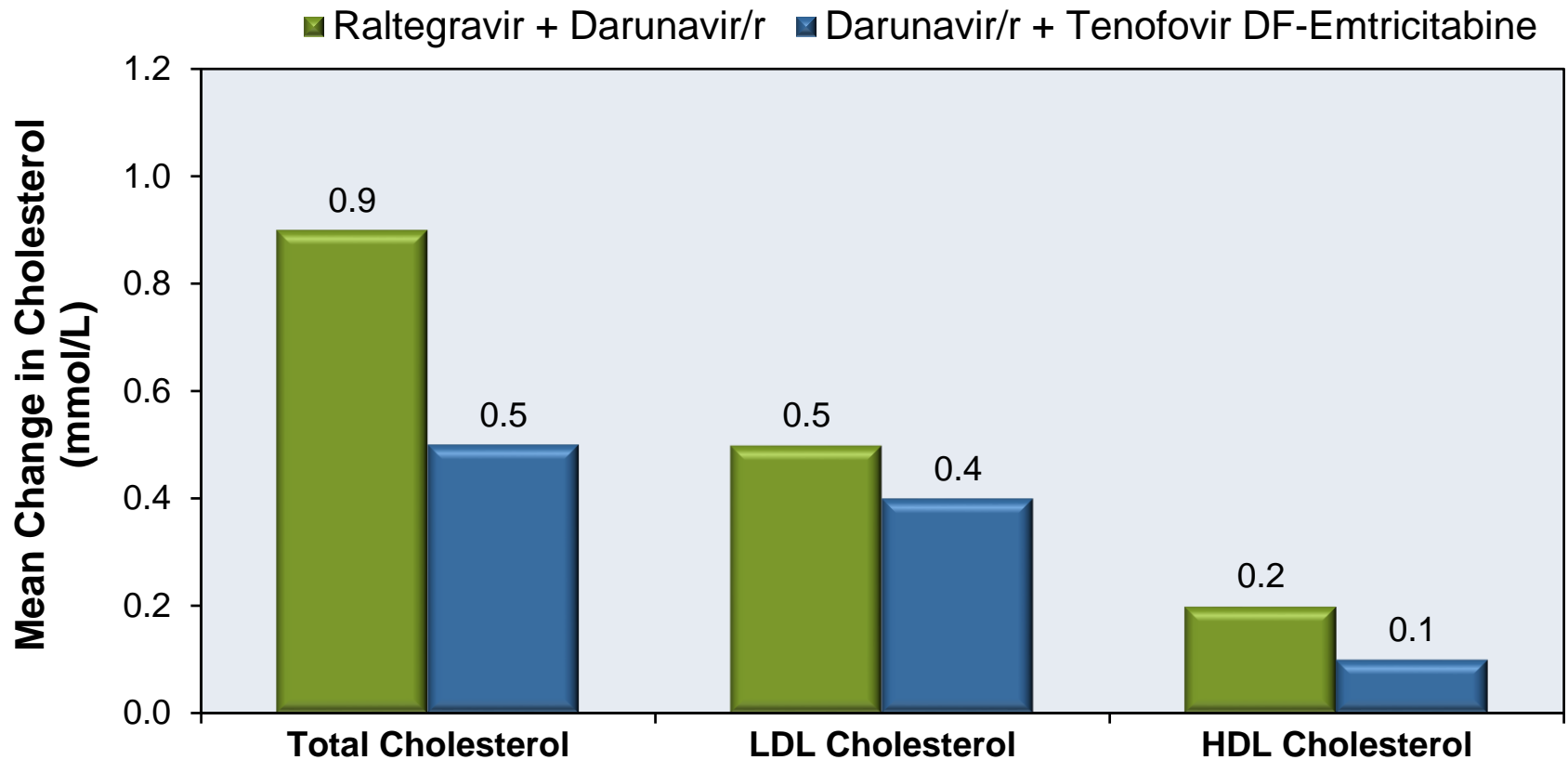
Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

Week 96: Treatment Failure, by HIV RNA and CD4 Count (combined effects)



Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

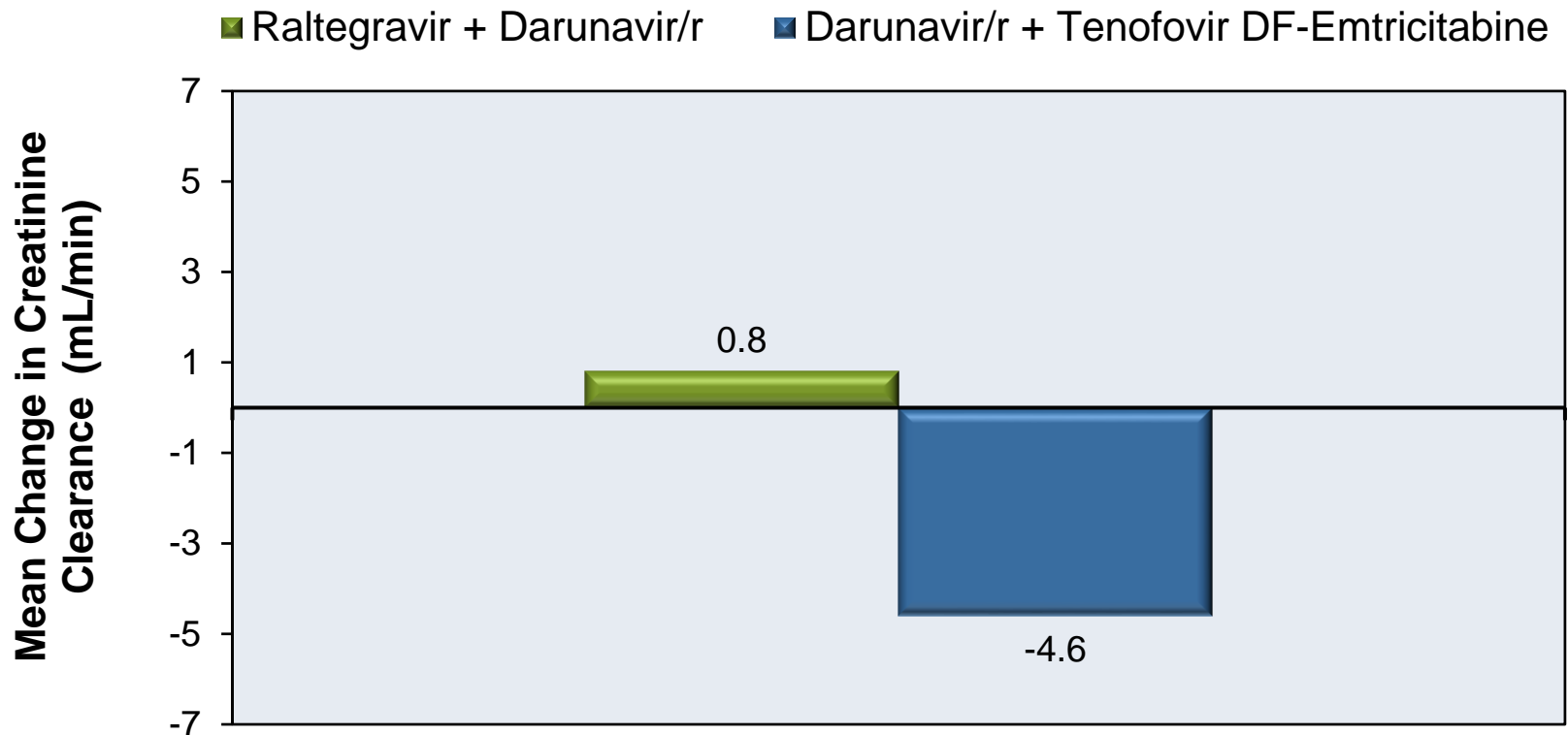
Week 96: Change in Lipids from Baseline



Source: Raffi F, et al. Lancet. 2014;384:1942-51.

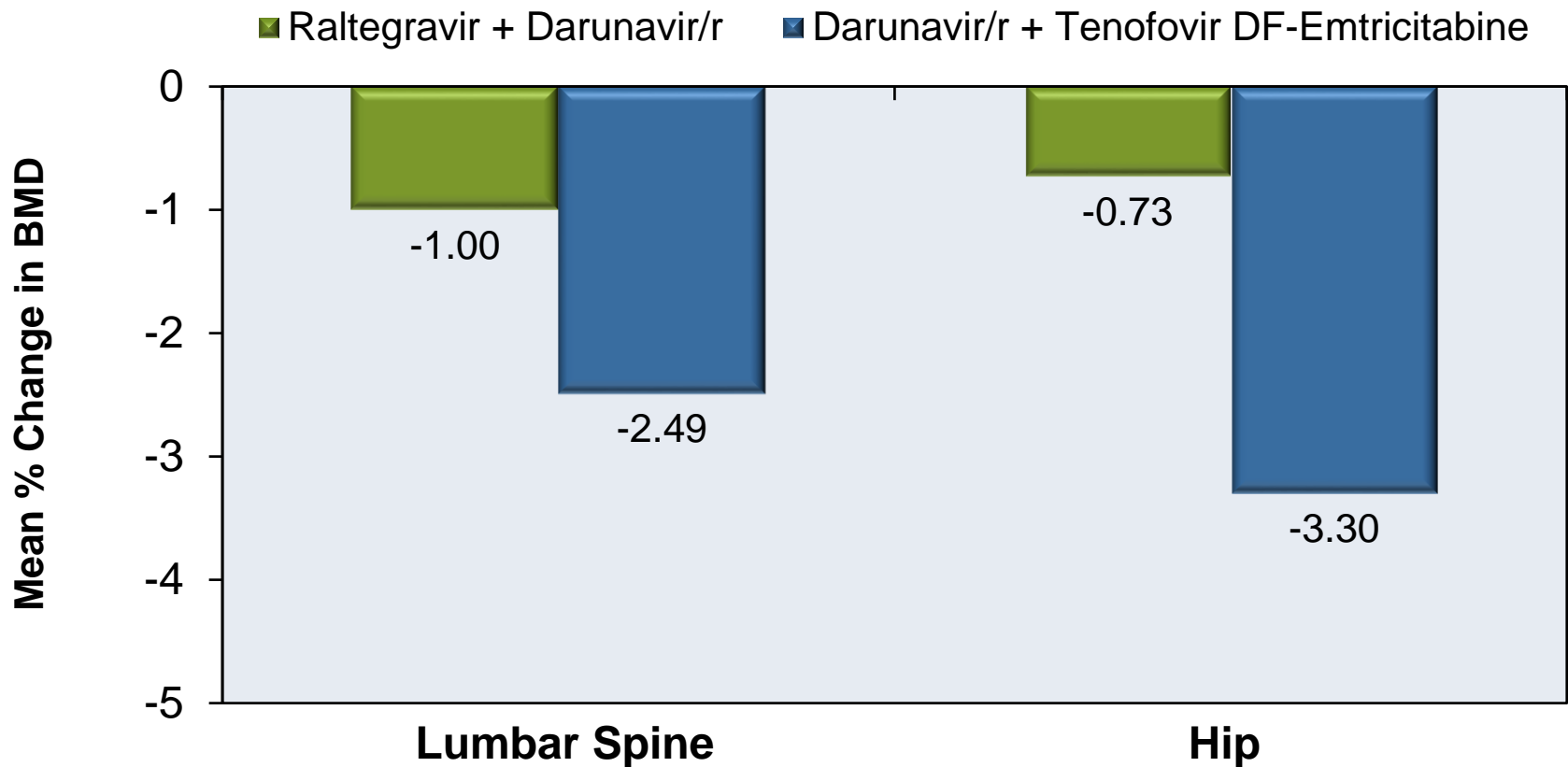
Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

Week 96: Change in Creatinine Clearance from Baseline



Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Substudy Result

Week 48: Changes in Spine and Hip Bone Mineral Density from Baseline



Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

Analysis of Virologic Failures and Emerging Genotypic Resistance

Genotype Resistance Testing in NEAT001/ANRS143

Resistance Testing and Results	RAL + DRV/r (n = 401)	DRV/r + TDF/FTC (n = 404)
Patients who underwent genotype resistance testing at virological failure	29	13
Major resistance mutations detected	6	0
Reverse transcriptase	1*	0
Protease	0	0
Integrase	5**	0

*K65R mutation; **N155H mutation

Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Conclusions

Interpretation: “Our NtRTI-sparing regimen was non-inferior to standard treatment and represents a treatment option for patients with CD4 cell counts higher than 200 cells per μL .”

Acknowledgment

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