

Tenofovir AF vs Tenofovir DF in HBeAg-Positive Study 110

Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Design

- **Background**

- Randomized double-blind placebo-controlled non-inferiority trial of tenofovir alafenamide (TAF) versus tenofovir disoproxil fumarate (TDF) in HBeAg-positive chronic hepatitis B patients

- **Subjects**

- N = 1473 with chronic hepatitis B eAg-positive infection
- HBV DNA level >20,000 IU/mL
- ALT >60 IU/L in men, >38 IU/L in women; <10 x ULN for both

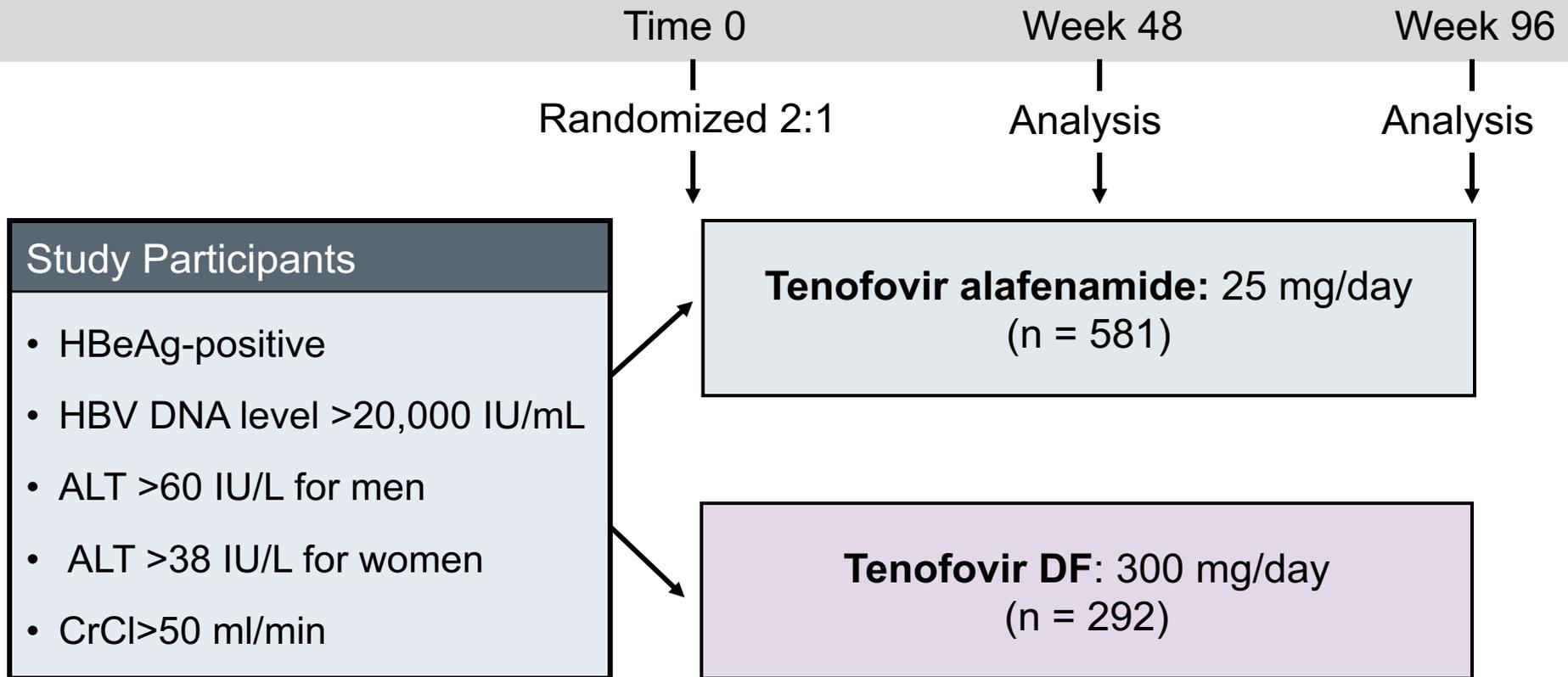
- **Regimens**

- Tenofovir AF 25 mg once daily with matching placebo
- Tenofovir DF 300 mg once daily with matching placebo

- **Study End-Point**

- HBV DNA level <29 IU/mL at week 48

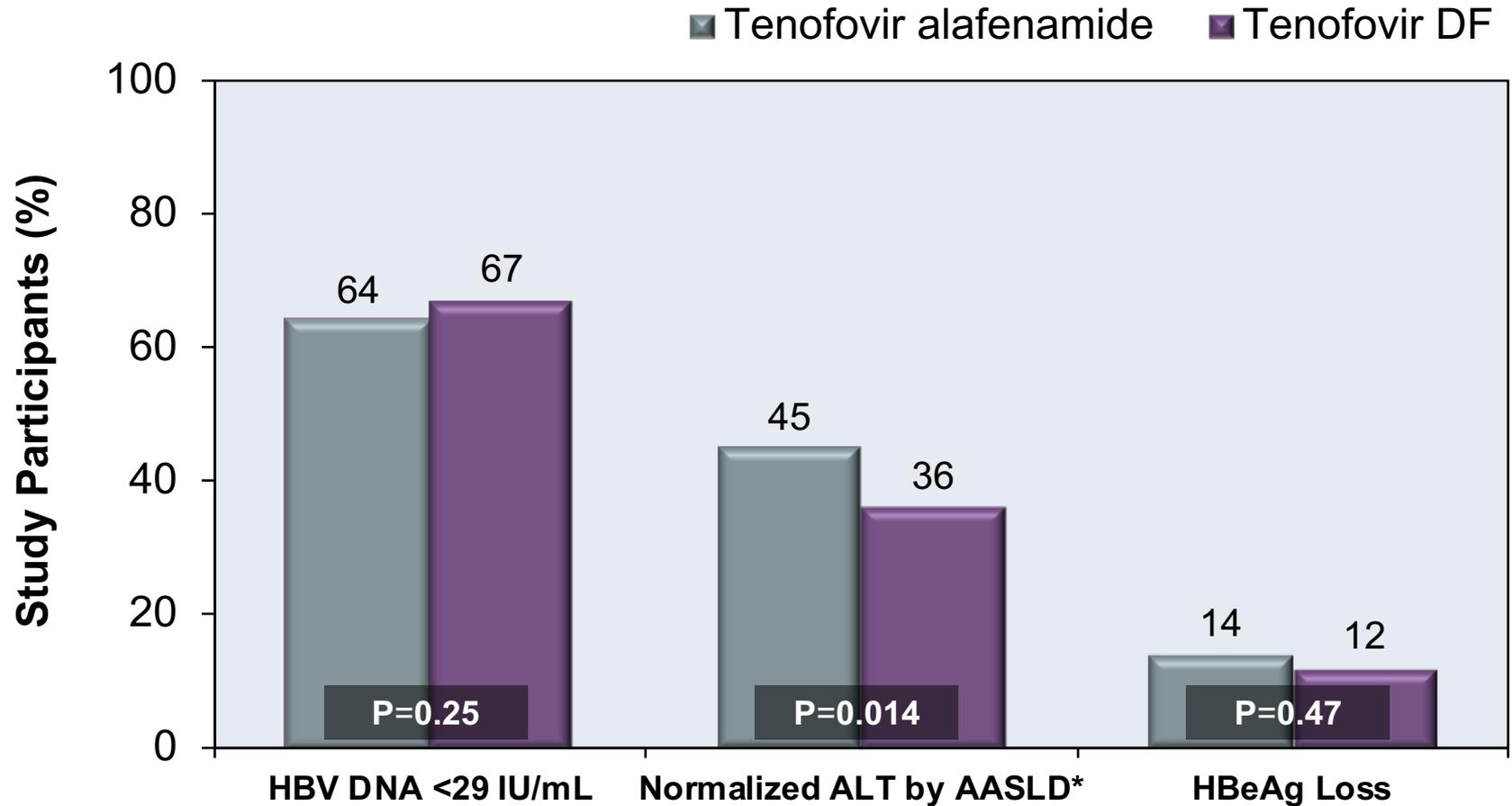
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Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Baseline Characteristics

Baseline Characteristic	Tenofovir AF (n = 581)	Tenofovir DF (n = 292)
Age, mean (\pm SD), years	38 (11)	38 (12)
Male, no. (%)	371 (64)	189 (65)
Race, no. (%)		
Asian	482 (83)	232 (79)
White	96 (17)	53 (18)
Other	3 (1)	7 (2)
ALT > ULN by central lab, no. (%)	537 (98)	288 (99)
HBV DNA, log ₁₀ IU/mL (\pm SD)	7.6 (1.3)	7.6 (1.4)
FibroTest score, mean (\pm SD)	0.34 (0.23)	0.32 (0.22)
Cirrhosis, no. (%)	41 (7)	24 (8)
Serum creatinine, mean (\pm SD)	0.81 (0.17)	0.82 (0.16)

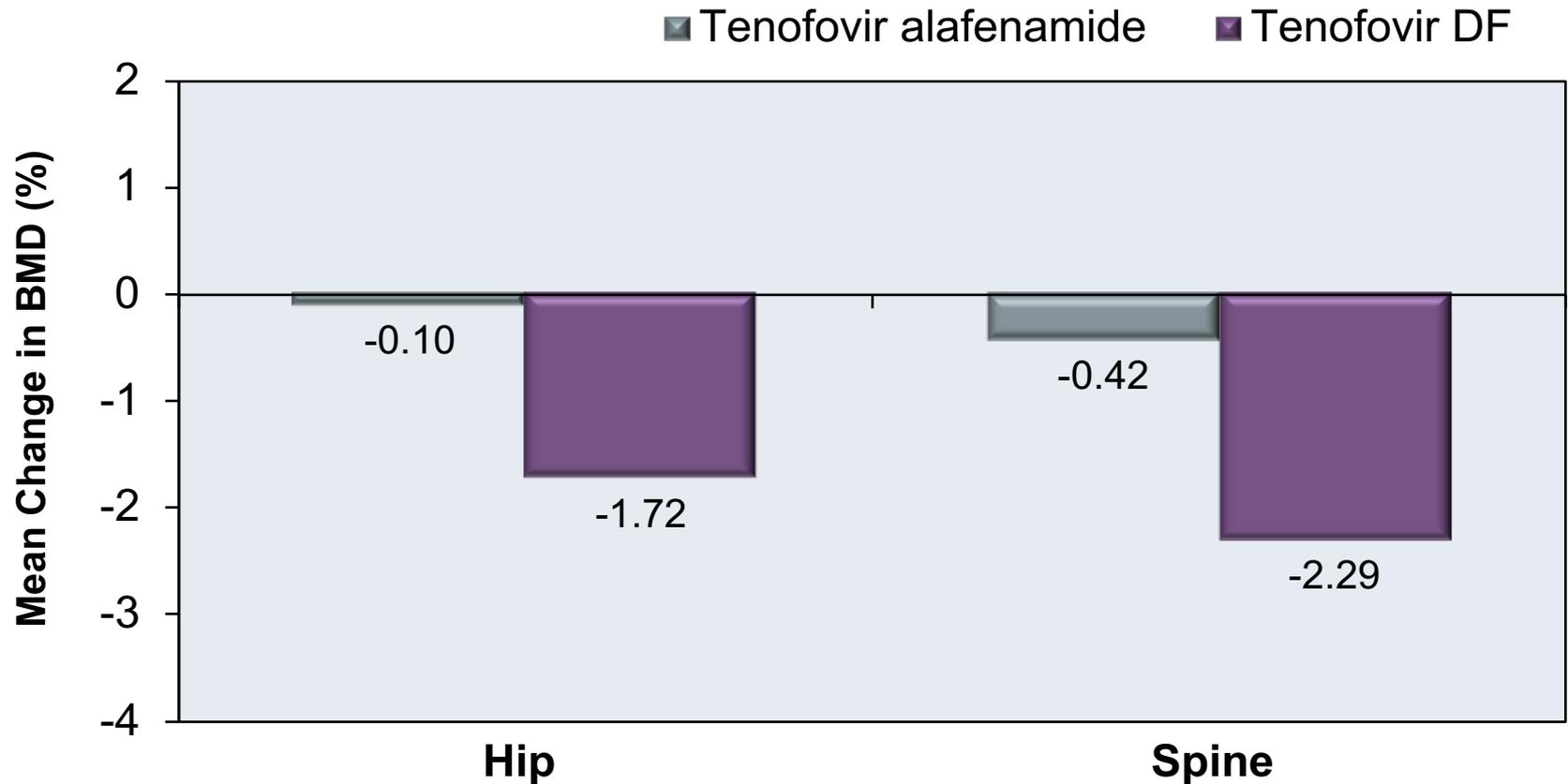
Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Results at Week 48



*Using normal ranges of ≤ 30 U/L for men and ≤ 19 U/L for women

Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Adverse Effects

Week 48 Changes in Bone Mineral Density (BMD)



Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Conclusion

Interpretation: “In patients with HBeAg-positive HBV infection, tenofovir alafenamide was non-inferior to tenofovir disoproxil fumarate, and had improved bone and renal effects. Longer term follow-up is needed to better understand the clinical impact of these changes.”