

Once Daily Etravirine in Treatment-Naïve Adults

08-2070 Trial

Once Daily Etravirine in Treatment-Naïve Adults 08-2070: Design

Study Design: 08-2070

- **Background:** Phase 2, single-arm trial assessing activity, safety, and tolerability of once-daily etravirine with tenofovir DF-emtricitabine in treatment-naïve adults with HIV
- **Inclusion Criteria (n = 79)**
 - Age ≥ 18 years
 - HIV RNA > 1000 copies/mL
 - Treatment-naïve
 - No resistance to etravirine or TDF-FTC
- **Treatment Arms**
 - Etravirine 400 mg QD + tenofovir-emtricitabine QD

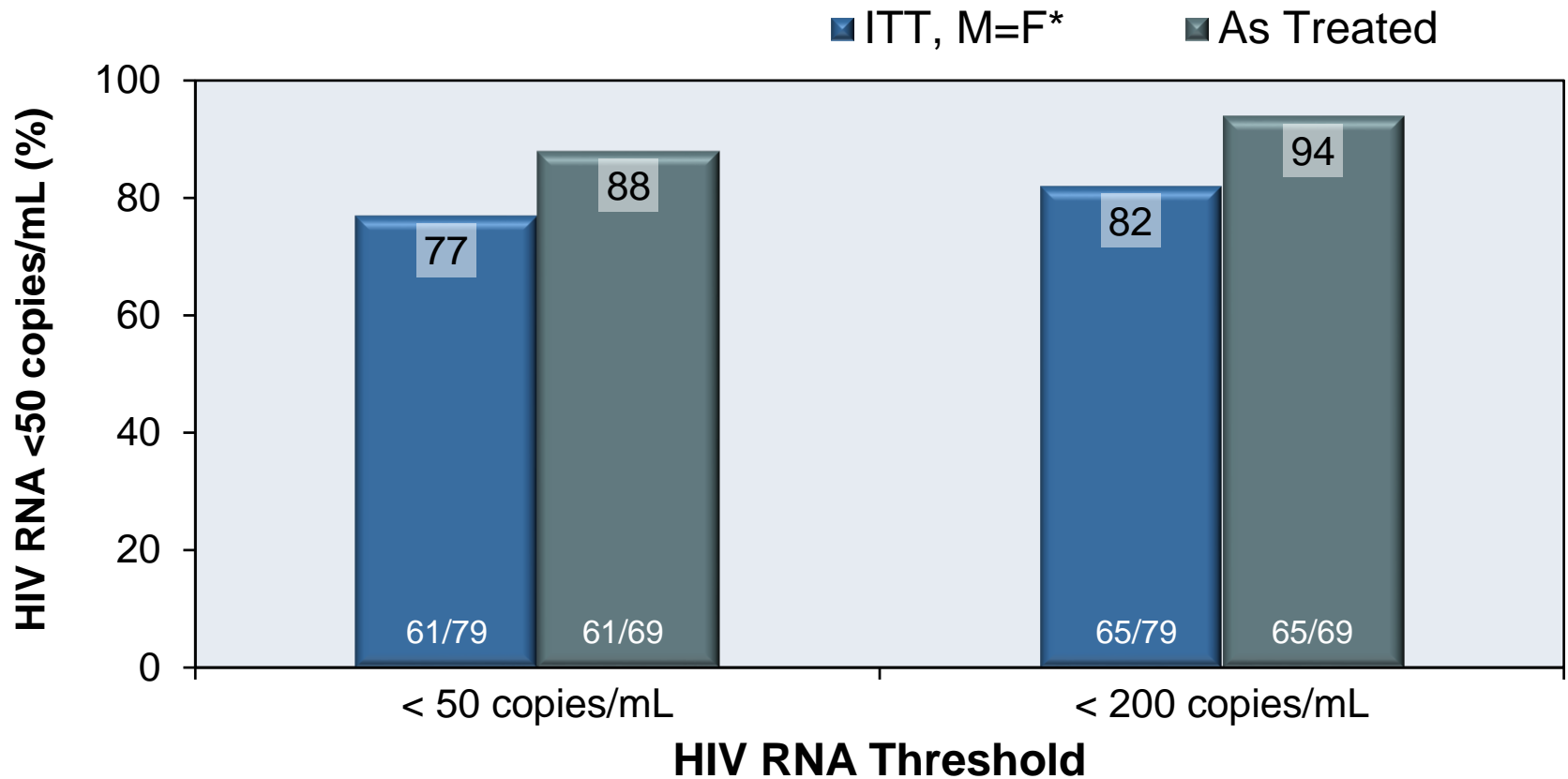
**Etravirine QD +
Tenofovir-emtricitabine QD**
(n = 79)

*ITT: Intent-to-Treat, M=F: missing equals failure

Source: Floris-Moore MA, et al. *Antivir Ther.* 2016;21:55-64.

Once Daily Etravirine in Treatment-Naïve Adults 08-2070: Result

Week 48: Virologic Response (all patients taking ETR + TDF-FTC)



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Source: Floris-Moore MA, et al. *Antivir Ther.* 2016;21:55-64.

Once Daily Etravirine in Treatment-Naïve Adults 08-2070: Result

Clinical Adverse Events and Laboratory Abnormalities through Week 48	
Variable	Frequency (%)
Rash (any grade)	5 (6.3)
Any grade 2 or higher event	18 (22.8)
New/worsened grade 3 or 4 sign/symptom	10 (12.7)
AST or ALT elevation (Grade 2 or higher)	5 (6.3)
Grade 2 creatinine elevation	2 (2.5)
New/worsened grade 3 or 4 laboratory abnormality	6 (7.6)
Etravirine discontinued due to toxicity	3 (3.8)

Once Daily Etravirine in Treatment-Naïve Adults 08-2070: Conclusions

Conclusions: “In this study of ARV-naïve HIV-positive adults, once-daily ETR with TDF/FTC had acceptable antiviral activity and was well-tolerated. Once-daily ETR may be a plausible option as part of a combination ARV regimen for treatment-naïve individuals.”

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