

Darunavir + RTV Monotherapy versus Triple Therapy
MONARCH Trial

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MONARCH: Study Design

Study Design: MONARCH

- **Background:** Randomized, phase II, open label trial evaluate change in cardiometabolic and endothelial function in patients with HIV infection switching to ritonavir-boosted darunavir (monotherapy) versus ritonavir-boosted darunavir + 2NRTIs (triple therapy)
- **Inclusion Criteria (n = 30)**
 - HIV RNA <50 copies/mL x 24 weeks on 3-drug ART
 - CD4 count >200 cells/mm³
 - CD4 count nadir >100 cells/mm³
 - No PI resistance or history of virologic failure
- **Treatment Arms**
 - Darunavir 800 mg QD + RTV 100 mg QD
 - Darunavir 800 mg QD + RTV 100 mg QD + 2 NRTIs

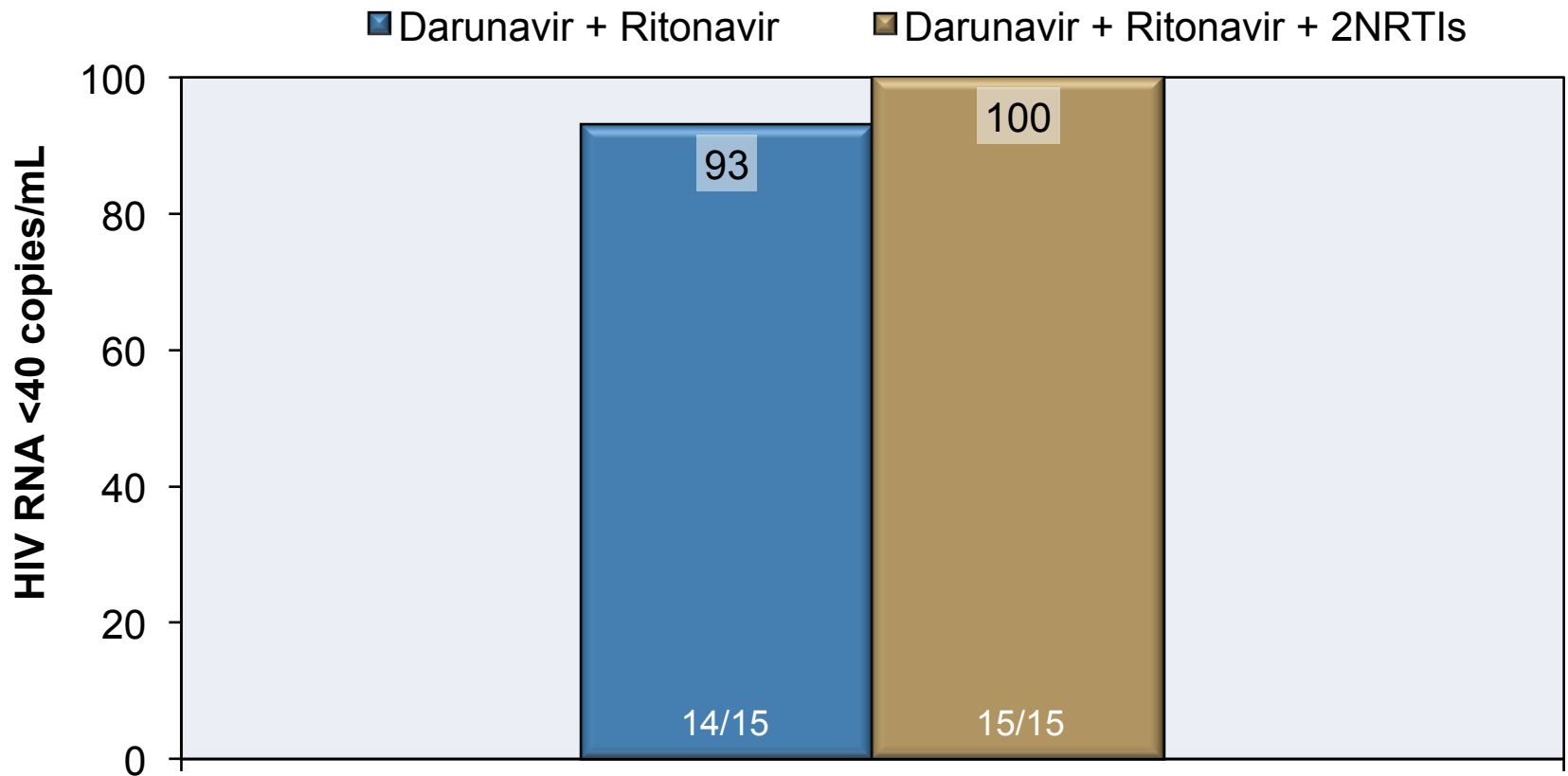
**Darunavir 800 mg QD
+ Ritonavir 100 mg QD**
(n = 15)

**Darunavir 800 mg QD
+ Ritonavir 100 mg QD
+ 2 NRTIs**
(n = 15)

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MONARCH: Result

Week 48: Virologic Response (Intent-to-Treat)

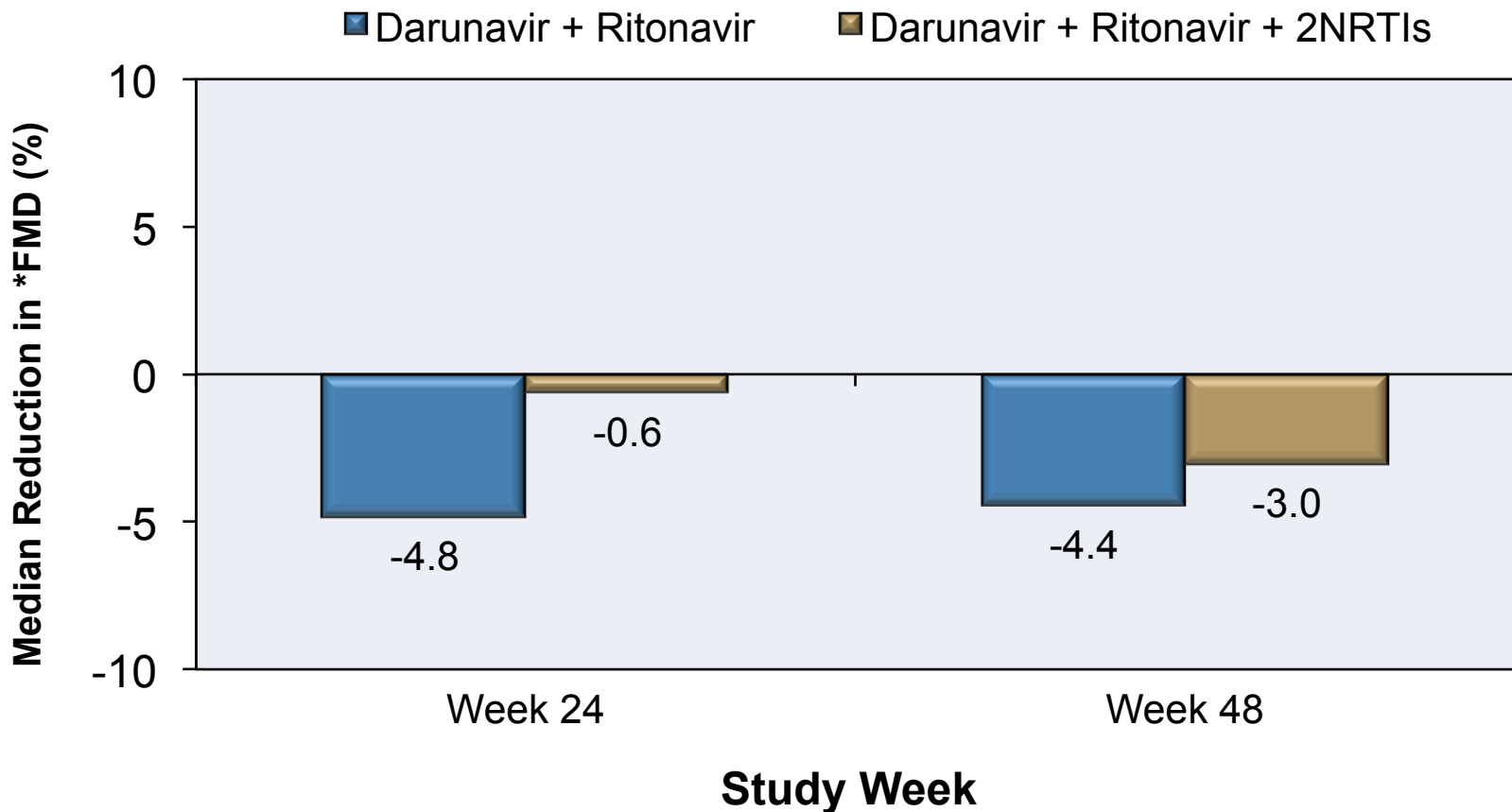


Source: Guaraldi G, et al. HIV Clin Trials. 2013;14:140-8.

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MONARCH: Result

Weeks 24 and 48: Change in Brachial Artery FMD



*FMD = Flow-mediated dilation

Source: Guaraldi G, et al. HIV Clin Trials. 2013;14:140-8.

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MONARCH: Conclusions

Conclusions: “In the MONARCH trial, switching from triple combination treatment to DRV/r, with or without nucleoside analogues, did not translate into clinically meaningful reductions in endothelial function as measured by FMD.”

Acknowledgment

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