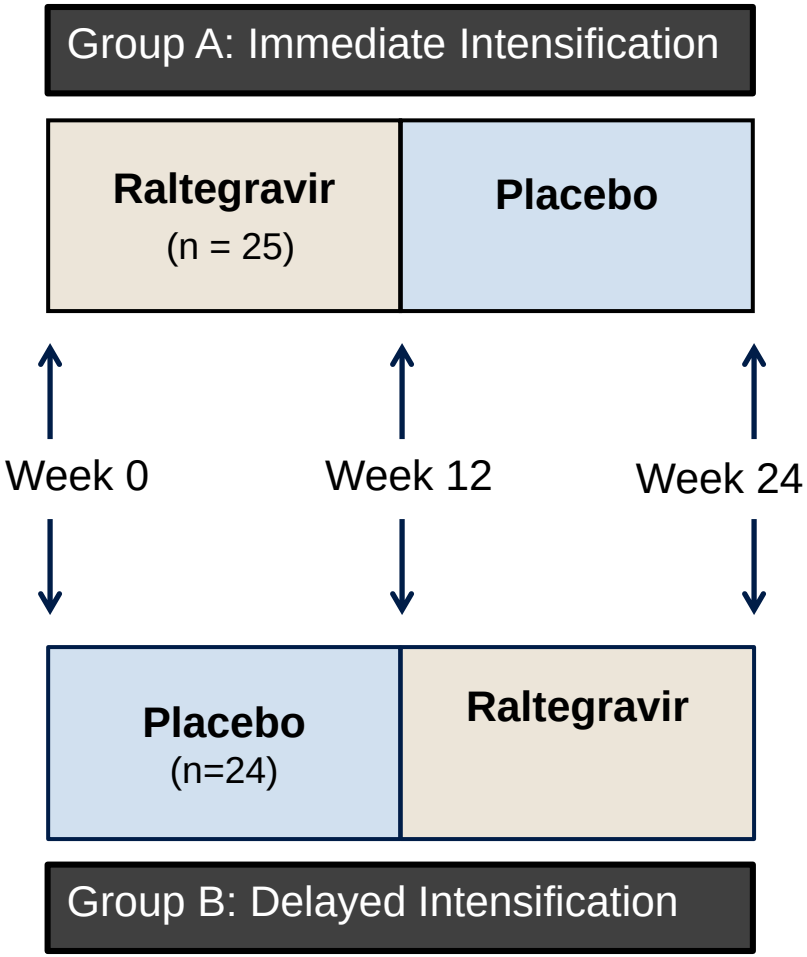
Raltegravir Intensification with Residual Low-Level Viremia

ACTG 5244 Trial

Raltegravir Intensification with Residual Low-Level Viremia
ACTG 5244: Study Design

Study Design: ACTG 5244

- **Background**: Randomized, double-blind, placebo-controlled, crossover trial evaluating effect of raltegravir intensification on patients taking ART with low-level residual viremia.
- **Inclusion Criteria (n = 53)**
  - ART-experienced but INSTI-naïve
  - On ART for ≥12 months on 2 NRTIs + either NNRTI or PI
  - HIV RNA <50 copies/mL for ≥6 months
  - Detectable viremia by single copy assay
  - Pretreatment HIV RNA >100,000 copies/mL
  - No history of documented virologic failure
  - Detectable viremia by single-copy assay
- **Treatment Arms (crossed over at 12 weeks)**
  - Group A: entry regimen + RAL 400 mg BID
  - Group B: entry regimen + placebo



Source: Gandhi RT, et al. PLoS Med. 2010;7:e1000321.

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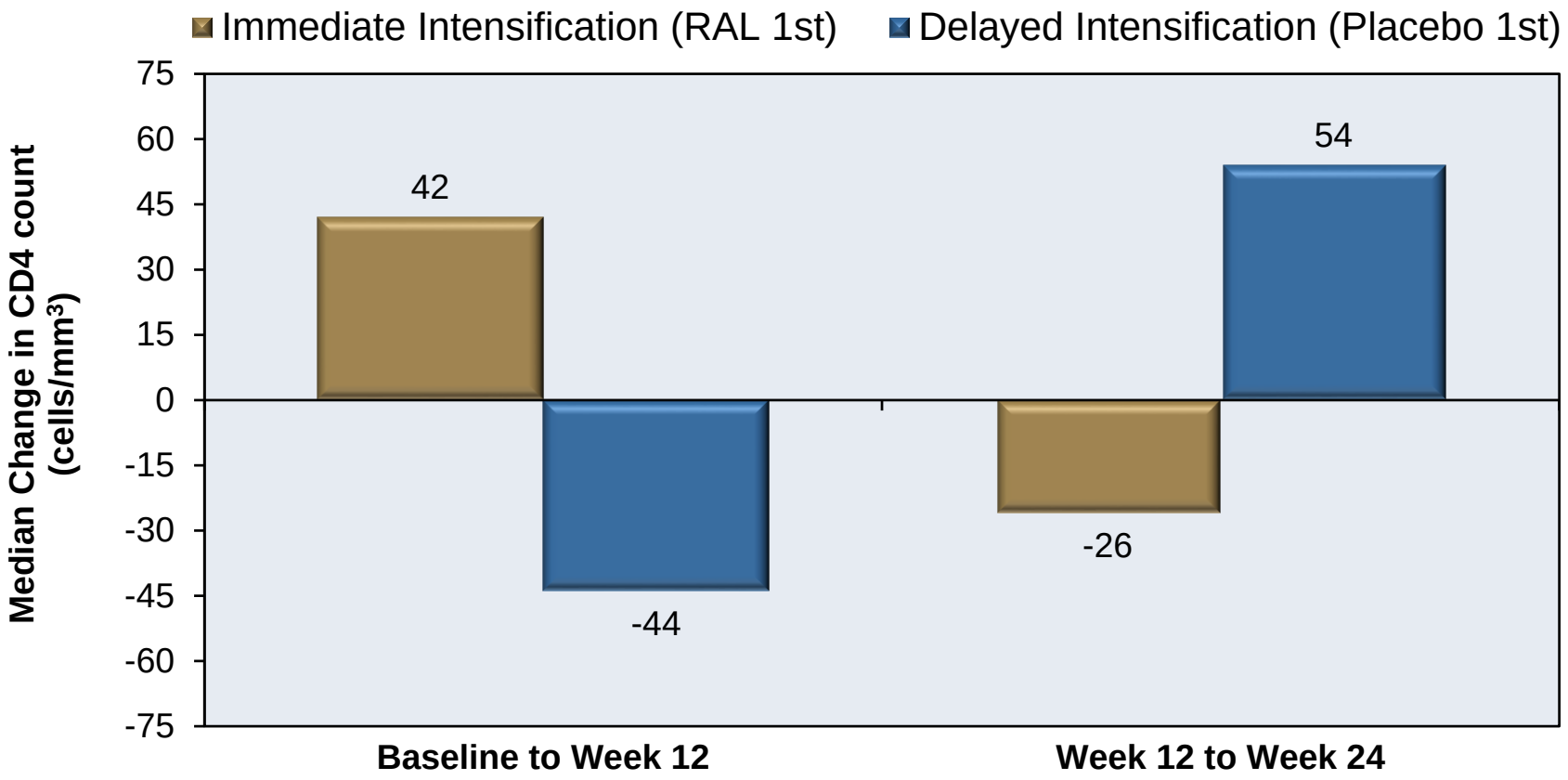
Raltegravir Intensification with Residual Low-Level Viremia
ACTG 5244: Results

Effect of Raltegravir Intensification on CD4 Counts



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Raltegravir Intensification with Residual Low-Level Viremia
ACTG 5244: Conclusions

Conclusion: “In this randomized, double-blind cross-over study, 12 weeks of raltegravir intensification did not demonstrably reduce low-level plasma viremia in patients on currently recommended ART. This finding suggests that residual viremia does not arise from ongoing cycles of HIV-1 replication and infection of new cells. New therapeutic strategies to eliminate reservoirs that produce residual viremia will be required to eradicate HIV-1 infection.”

Source: Gandhi RT, et al. PLoS Med. 2010;7:e1000321.

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