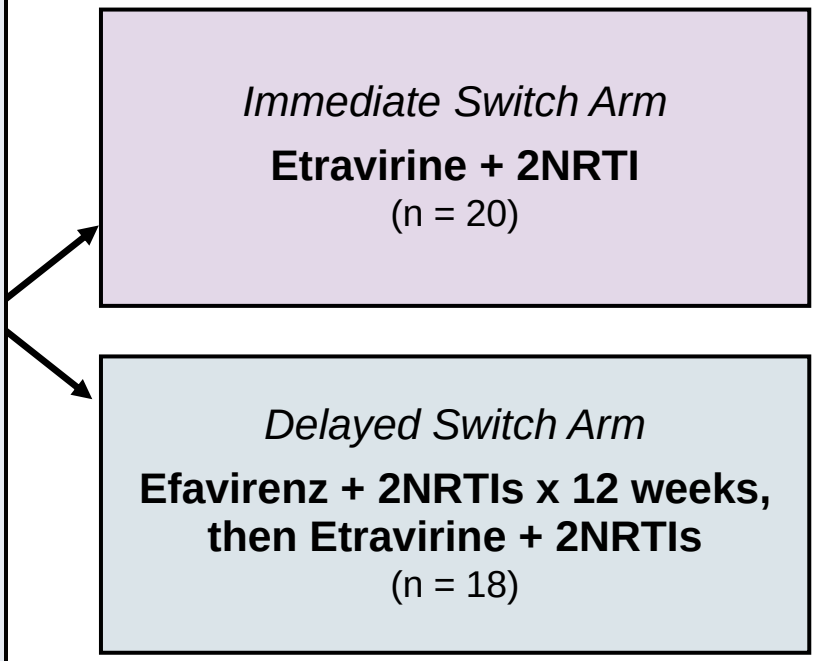
Switch to Etravirine from Efavirenz due to CNS Toxicity

SSAT-029 STUDY

Switch to Etravirine from Efavirenz Due to CNS Toxicity
SSAT-029: Design

Study Design: SSAT-029

- **Background**: Randomized, double-blind, phase IV trial evaluating the impact of switching from etravirine to efavirenz on central nervous system (CNS) symptoms on a stable, fully suppressive efavirenz-based regimen
- **Inclusion Criteria (n = 38)**
  - On efavirenz plus 2NRTIs >12 weeks
  - Ongoing CNS symptoms
  - HIV RNA <50 copies/mL
  - CD4 count >50 cells/mm^3
  - No previous exposure to etravirine or rilpivirine
- **Treatment Arms**
  - ETR + EFV-placebo + 2NRTI x 12 weeks, then open-label ETR + 2NRTIs
  - EFV + ETR-placebo + 2NRTI x 12 weeks, then switch to open-label ETR + 2NRTIs

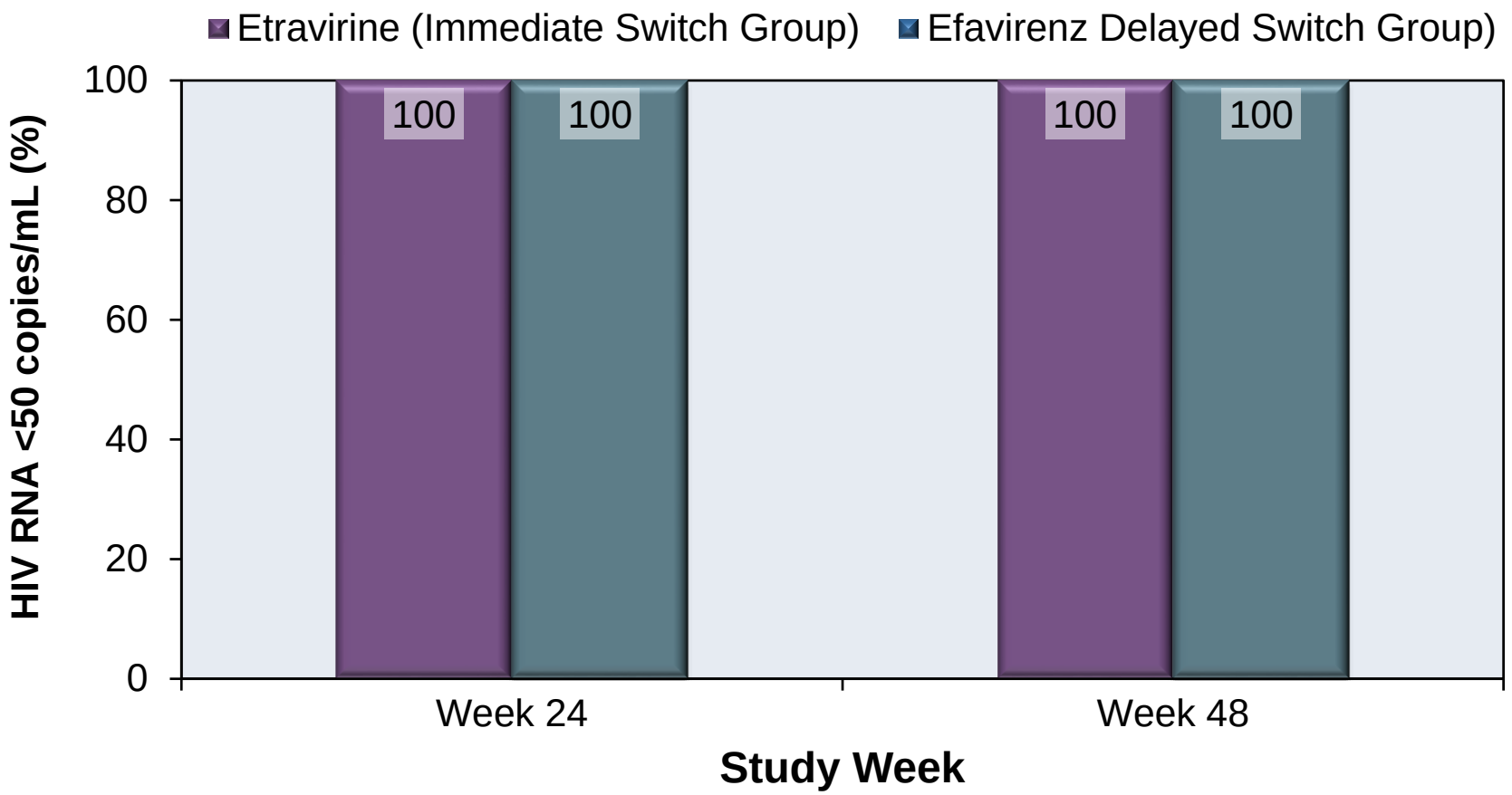


Source: Waters L, et al. AIDS. 2011;25:65-71.

Switch to Etravirine from Efavirenz Due to CNS Toxicity

SSAT-029: Result

Week 24 and 48: Virologic Response (on-treatment analysis)

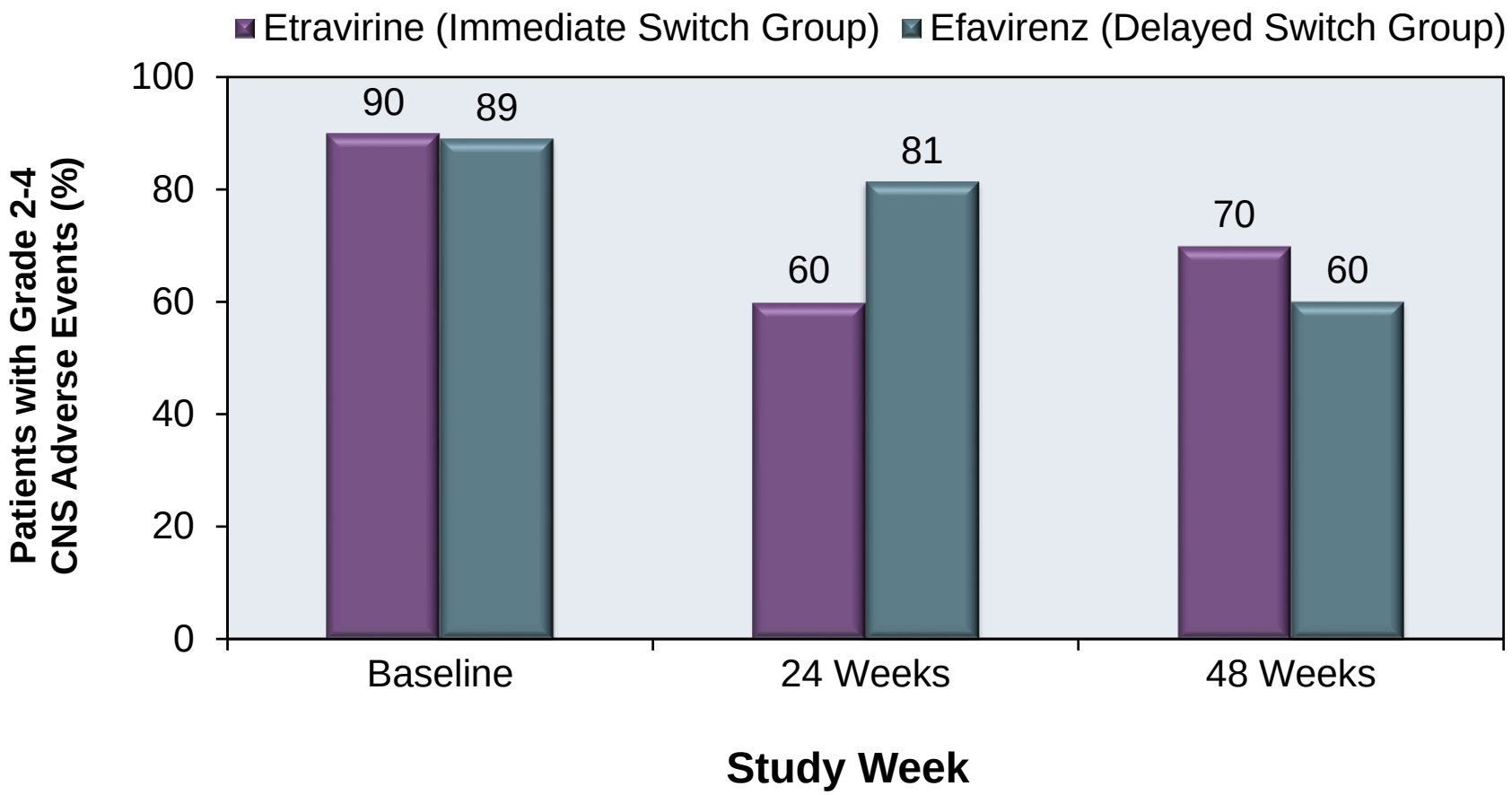


Source: Waters L, et al. AIDS. 2011;25:65-71.

Switch to Etravirine from Efavirenz Due to CNS Toxicity

SSAT-029: Result

Change in CNS Adverse Events, by Study Group

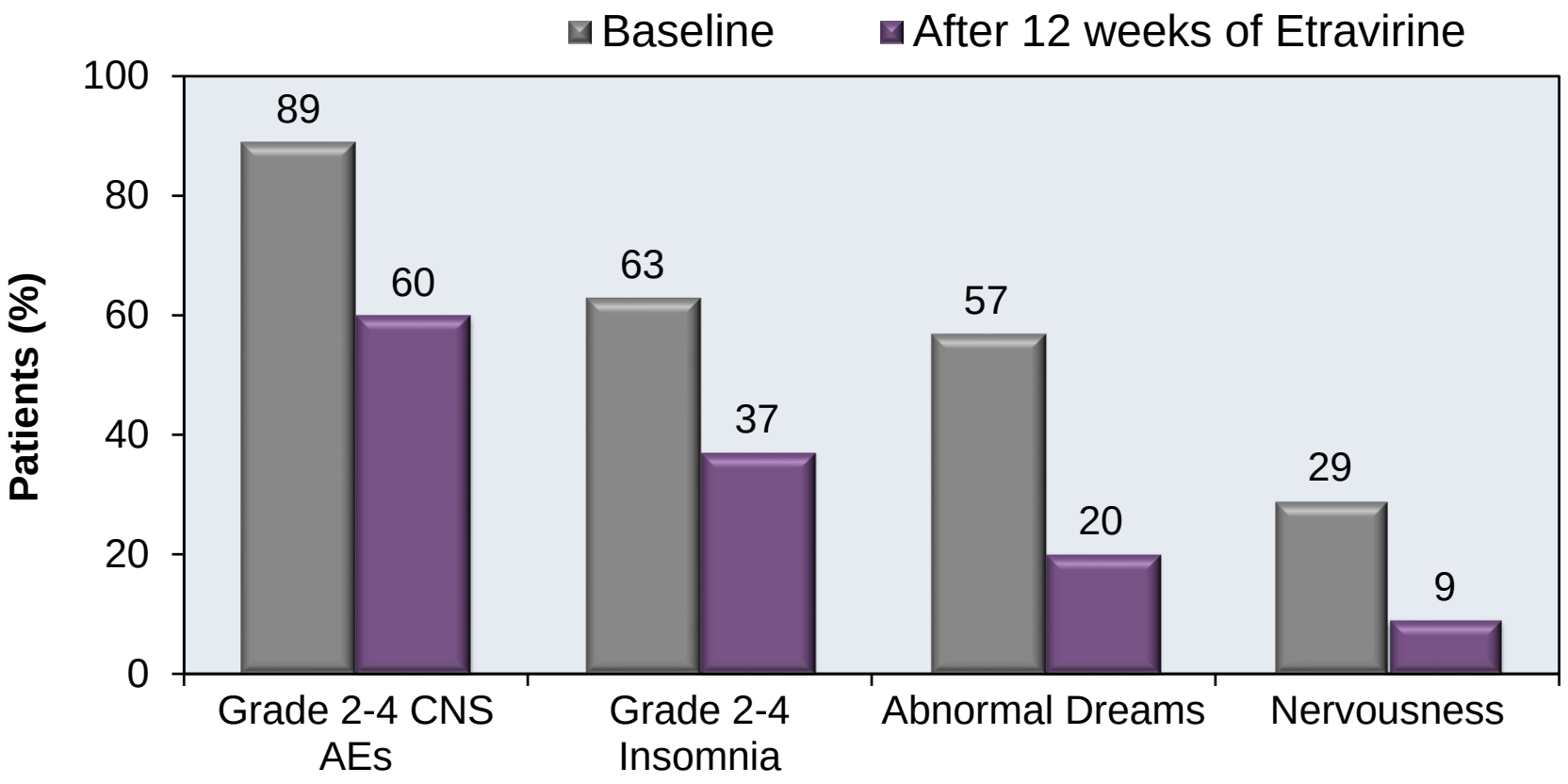


Source: Waters L, et al. AIDS. 2011;25:65-71.

Switch to Etravirine from Efavirenz Due to CNS Toxicity

SSAT-029: Result

Change in CNS Adverse Events: Combined Analyses



Source: Waters L, et al. AIDS. 2011;25:65-71.

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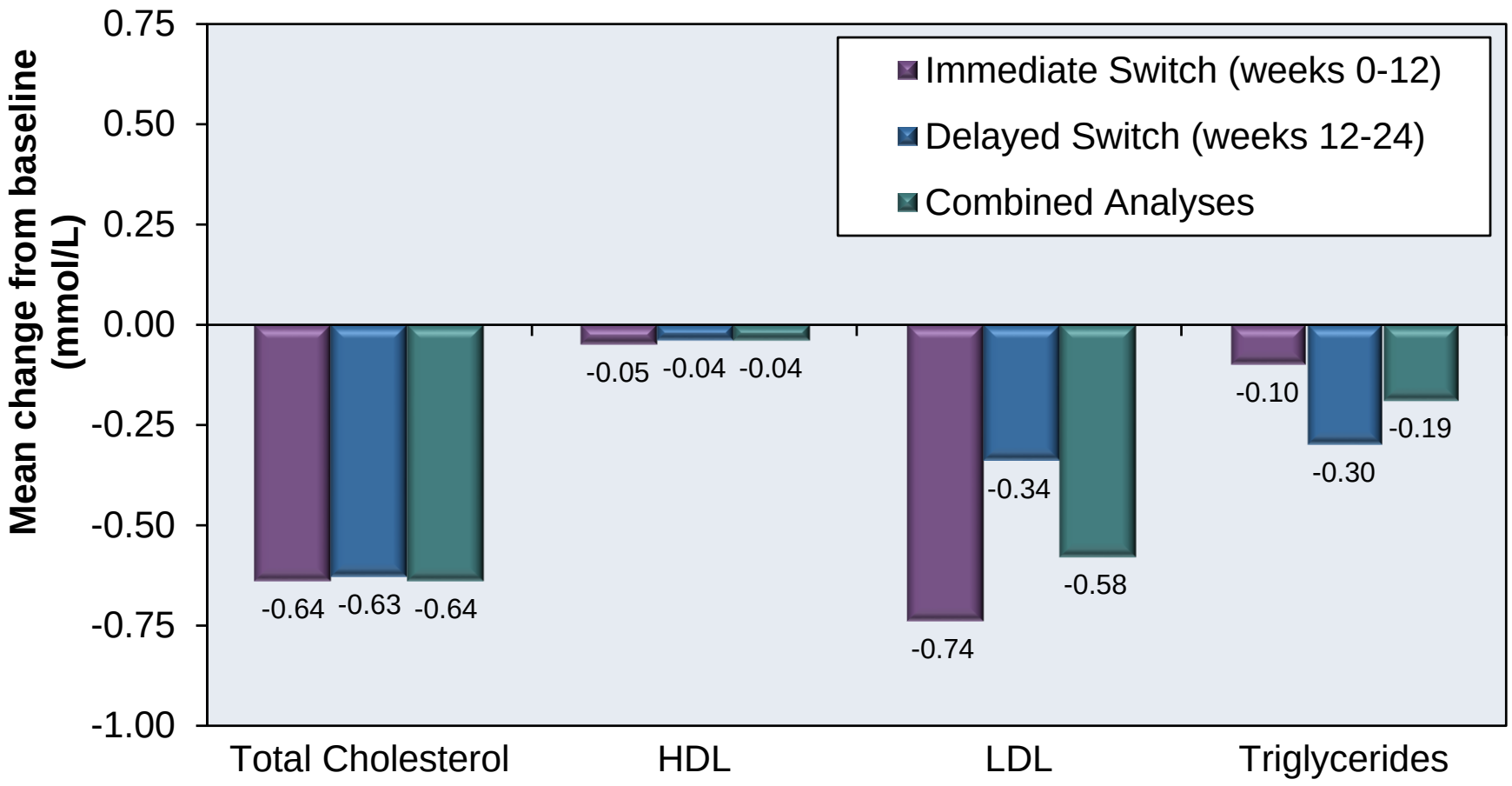
SSAT-029: Result

Lipid Changes After 12 Weeks of Etravirine



Source: Waters L, et al. AIDS. 2011;25:65-71.

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Switch from Efavirenz to Etravirine
SSAT-029: Conclusions

Conclusion: “Switching efavirenz to etravirine led to a significant reduction in overall grade 2-4 CNS adverse events, including insomnia, abnormal dreams and nervousness as individual adverse event. Lack of improvement for some events suggests other causative factors.”

Source: Waters L, et al. AIDS. 2011;25:65-71.

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

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