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/mm³
  - 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

**Immediate Switch Arm**

- Etravirine + 2NRTI
- (n = 20)

**Delayed Switch Arm**

- Efavirenz + 2NRTIs x 12 weeks, then Etravirine + 2NRTIs
- (n = 18)

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SSAT-029: Result

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

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SSAT-029: Result

Change in CNS Adverse Events, by Study Group

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SSAT-029: Result

Change in CNS Adverse Events: Combined Analyses

![Graph showing the change in CNS adverse events after 12 weeks of Etravirine compared to baseline.](chart)

- **Grade 2-4 CNS AEs**: Baseline 89%, After 12 weeks 60%
- **Grade 2-4 Insomnia**: Baseline 63%, After 12 weeks 37%
- **Abnormal Dreams**: Baseline 57%, After 12 weeks 20%
- **Nervousness**: Baseline 29%, After 12 weeks 9%

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SSAT-029: Result

Lipid Changes After 12 Weeks of Etravirine

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.”

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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