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

**Immediate Switch Arm**

Etravirine + 2NRTI
(n = 20)

**Delayed Switch Arm**

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

Switch to Etravirine from Efavirenz Due to CNS Toxicity

SSAT-029: Result

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

Switch to Etravirine from Efavirenz Due to CNS Toxicity

SSAT-029: Result

Change in CNS Adverse Events, by Study Group

Switch to Etravirine from Efavirenz Due to CNS Toxicity

SSAT-029: Result

Change in CNS Adverse Events: Combined Analyses

Switch to Etravirine from Efavirenz Due to CNS Toxicity

SSAT-029: Result

Lipid Changes After 12 Weeks of Etravirine

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.”

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