SERUM SODIUM LEVELS AND RELATED TREATMENT-EMERGENT ADVERSE EVENTS DURING ESLICARBAZEPINE ACETATE USE IN ADULTS WITH EPILEPSY

Wechsler RT, et al. *Epilepsia* 2019;60:1341–52

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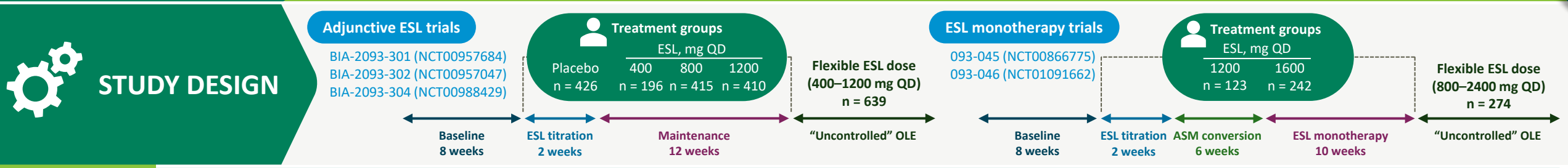
OBJECTIVE

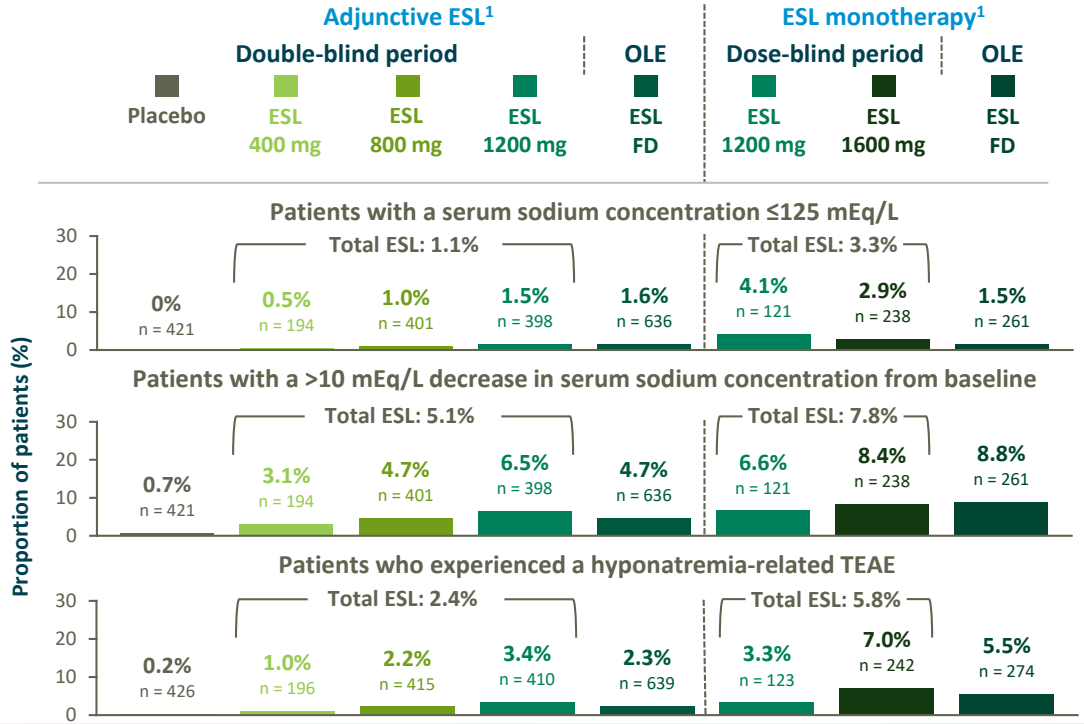
Conduct a post hoc, exploratory analysis to examine the frequency of hyponatremia and potentially related symptoms in five phase III clinical trials of ESL in adults with refractory focal seizures

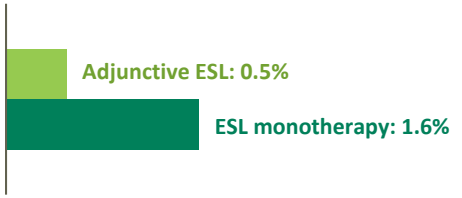
STUDY DESIGN



RESULTS

SAFETY





- Hyponatremia appeared to be more frequent in the **monotherapy** (vs adjunctive therapy) trials of ESL
  - There was no placebo control in the monotherapy trials
- The majority of patients with an investigator-reported TEAE of "hyponatremia" or "blood sodium decreased" did **NOT** have a corresponding low laboratory serum sodium measurement (≤125 mEq/L)
- Some symptoms of hyponatremia (e.g., nausea and vomiting) were more frequent in patients with low serum sodium measurements

>66% of patients taking ESL had minimum postdose serum sodium measurements >135 mEq/L, that is no evidence of hyponatremia

CONCLUSIONS

Reductions in serum sodium concentrations and hyponatremia-related TEAEs occurred in a small number of patients taking ESL. Suspected hyponatremia should be confirmed and monitored via serum sodium concentration measurements

Abbreviations: ASM, antiseizure medication; ESL, eslicarbazepine acetate; FD, flexible dosing; OLE, open-label extension; QD, once-daily; TEAE, treatment-emergent adverse event. [1]Reprinted with permission from John Wiley and Sons. Wechsler RT, et al. Serum sodium levels and related treatment-emergent adverse events during eslicarbazepine acetate use in adults with epilepsy. Epilepsia 2019;60:1341–52. Copyright © 2019.

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