SAFETY AND TOLERABILITY OF ADJUNCTIVE ESLICARBAZEPINE ACETATE IN PEDIATRIC PATIENTS (AGED 4–17 YEARS) WITH FOCAL SEIZURES

Mintz M, et al. *J Child Neurol* 2020;35:265–73

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OBJECTIVE

Evaluate the safety and tolerability of adjunctive ESL in two randomized, double-blind, placebo-controlled studies of pediatric patients (aged 4–17 years) with refractory focal seizures

STUDY DESIGN[1]

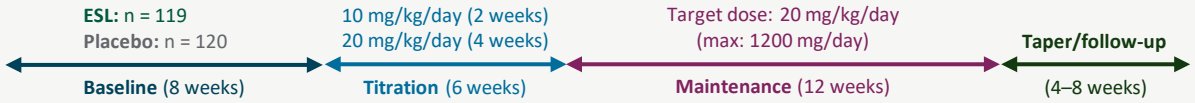
Pooled data from clinical trials in children aged 4–17 years

Study 208* (NCT01527513)

Children aged 6–16 years with ≥2 focal seizures in the month prior to screening and IQ ≥70

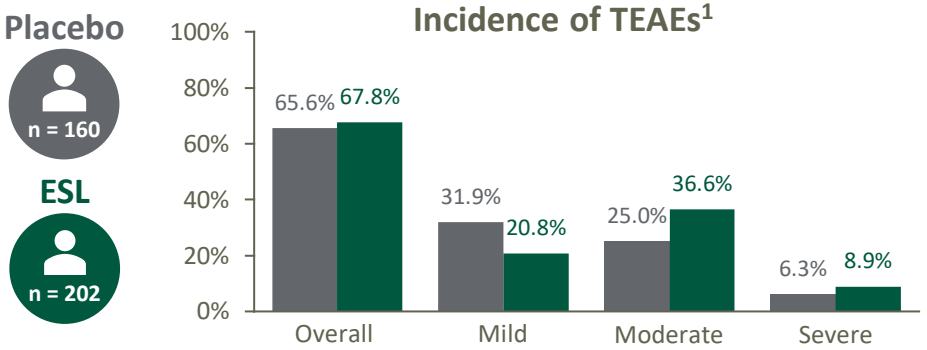
Study 305* (NCT00988156)

Children aged 2–18 years with ≥4 focal seizures in the month prior to enrollment

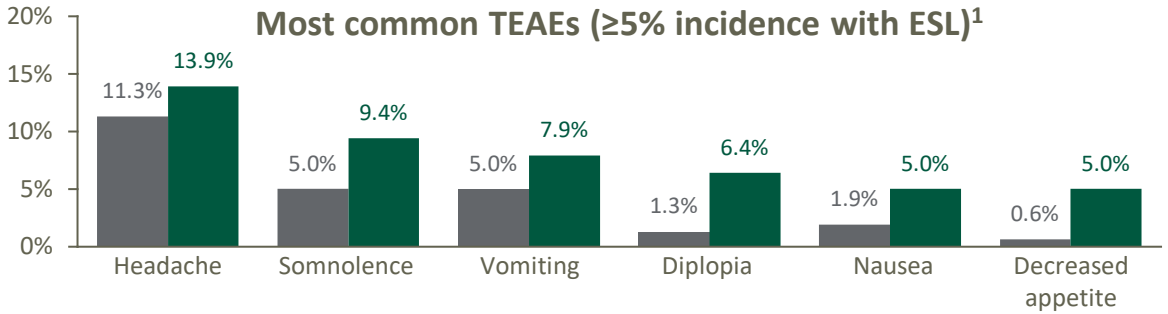


RESULTS

SAFETY



The overall incidence of TEAEs was similar between the ESL and placebo groups



TEAEs related to allergic reaction, hyponatremia, hypothyroidism, cytopenia, seizure exacerbation, cognitive dysfunction, psychiatric disorders, or suicide occurred infrequently (<9%)

The overall incidences of SAEs and TEAEs leading to discontinuation were higher with ESL versus placebo

Two deaths were reported:

ESL

1 patient

- Due to cluster seizures resulting in herniation of the cerebellar tonsils
- Cluster seizures were considered "not related" to treatment with ESL by the investigator and "possibly related" by the sponsor

Placebo

1 patient

- Due to asphyxia (a plastic bag was found in the patient's mouth)

CONCLUSIONS

Adjunctive ESL was generally well tolerated in children aged 4–17 years with focal seizures, and the safety profile of ESL in children was comparable to that observed in adults

*Adjunctive ESL was also evaluated in an earlier open-label study in pediatric patients (Study 202). Abbreviations: ESL, eslicarbazepine acetate; IQ, intelligence quotient; OLE, open-label extension; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

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