

Levetiracetam vs Phenytoin for second line treatment of pediatric convulsive status epilepticus (ECLIPSE): a multicentre, open label, randomised trial.

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Background & Objectives: Phenytoin is recommended as a drug of choice for second line treatment of Pediatric convulsive status epilepticus worldwide. Some evidence suggests that Levetiracetam could be an effective and safer alternative. The study compares the efficacy and safety of Phenytoin and Levetiracetam for second-line management of paediatric convulsive status epilepticus.

Methods: This open-label, randomised clinical trial was undertaken at 30 UK emergency departments at secondary and tertiary care centres. Participants aged 6 months to under 18 years, with convulsive status epilepticus requiring second-line treatment, were randomly assigned (1:1) to receive levetiracetam (40 mg/kg over 5 min) or phenytoin (20 mg/kg over at least 20 min). The primary outcome was time from randomisation to cessation of convulsive status epilepticus, analysed in the modified intention-to-treat population.

ACADEMIC P.E.A.R.L.S

Pediatric Evidence And Research Learning Snippet



Levetiracetam vs Phenytoin for Pediatric Status Epilepticus. Which one is better?

RESULTS: A total of 1432 patients were assessed for eligibility. After exclusion of ineligible patients, 404 patients were randomly assigned.

- After exclusion of those who did not require second-line treatment and those who did not consent, 286 randomised participants were treated and had available data: 152 allocated to levetiracetam, and 134 to phenytoin.
- Convulsive status epilepticus was terminated in 106 (70%) children in the levetiracetam group and in 86 (64%) in the phenytoin group.
- Median time from randomisation to cessation of convulsive status epilepticus was 35 min (IQR 20 to not assessable) in the levetiracetam group and 45 min (24 to not assessable) in the phenytoin group (hazard ratio 1.20, 95% CI 0.91-1.60; p=0.20).
- One participant who received levetiracetam followed by phenytoin died as a result of catastrophic cerebral oedema unrelated to either treatment.
- One participant who received phenytoin had serious adverse reactions related to study treatment and increased focal seizures and decreased consciousness considered to be medically significant.

CONCLUSION: Although levetiracetam was not significantly superior to phenytoin, the results, together with previously reported safety profiles and comparative ease of administration of levetiracetam, suggest it could be an appropriate alternative to phenytoin as the first-choice, second-line anticonvulsant in the treatment of paediatric convulsive status epilepticus.

EXPERT COMMENT

“This study confirms the safety and efficacy of Levetiracetam as an alternative agent for second line treatment of Pediatric status epilepticus when benzodiazepines failed to control the seizure. It is not superior to Phenytoin in the terms of seizure control, but safety profile is excellent”.

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With warm regards,

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Reference

Mark D Lyttle, Naomi E A Rainford, Carrol Gamble, Shrouk Messahel, Amy Humphreys, Helen Hickey, et al.
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