

THE EFFICACY AND SAFETY OF LEVETIRACETAM VERSUS FOSPHENYTOIN IN CONVULSIVE STATUS EPILEPTICUS: AN OPEN LABEL CLINICAL TRIAL IN DHAKA MEDICAL COLLEGE HOSPITAL

MD. AMIRUL ISLAM¹, KAZI GIAS UDDIN AHMED¹, REAZ MAHMUD²

Background: Status epilepticus (SE) is often referred to the “maximum expression of epilepsy”, but status is also a severe expression of an acute brain insult or systemic disturbance, which leads to excessive hyper-excitation of nervous tissue. SE is an emergency, life-threatening medical condition that may cause irreversible cerebral damage. Therefore, the rapid and secured cessation of seizures and resuscitation is crucial. Levetiracetam (LEV) and Fosphenytoin (FPHT) both are recommended as a second-line treatment for benzodiazepine refractory status epilepticus. As a newer antiepileptic drug levetiracetam (LEV) reportedly has similar efficacy, but higher safety profile. Considering the data scarcity in our country context, this study assessed the efficacy and safety between levetiracetam and fosphenytoin among benzodiazepine refractory convulsive status epilepticus patients. **Methods:** This prospective hospital based open label interventional study was conducted in Dhaka Medical College Hospital, Dhaka for two years period from July 2022 to June 2024 following approval of this protocol from ethical review committee of DMC. Status epilepticus was diagnosed according to the criteria of ILAE (International League against Epilepsy) task force on classification of status epilepticus (2015). Randomization was done at 1:1 into a parallel group. A total of 62 patients with convulsive status epilepticus were divided into 2 groups on their antiepileptic medication. Group A included convulsive status epilepticus patients on fosphenytoin (n=31) and group B included convulsive status epilepticus patients on levetiracetam (n=31). A detailed history, thorough clinical examination, and necessary investigations were carried out in each patient. Patients were followed up at 30 minutes, 24 hours and 7 days or hospital discharge whichever came first after receiving medication and following outcome were assessed: seizure cessation rate at 30 minutes, seizure recurrence rate, endotracheal intubation rate, all cause in-hospital mortality, adverse effects of drugs and financial burden. **Results:** Mean ($\pm$ SD) age of the patients was 40.65 ± 18.47 years in group-A and 44.03 ± 18.14 years in group-B. Male patients were predominant in both groups (64.5% and 74.2% respectively in group-A and B). In type of seizure, most of the patients had generalized tonic clonic seizure in both groups (71.0% and 77.4% respectively in group A and B). Both groups were statistically similar in terms of socio-demographic characteristics, co-morbidities, and disease profile ($p > 0.05$). After 30 minutes following trial drug infusion, the primary outcome of seizure cessation rate was statistically similar in both groups (51.6% vs 64.5%, p value 0.303). Seizure recurrence within 24 hours was statistically similar in both groups (12.9% vs 16.1%, p value 0.718) but seizure free interval in case of seizure recurrence was significantly higher in levetiracetam group (92.5 minutes vs 230.0 minutes respectively in group-A and B, p value 0.045). Also, there was no statistically significance difference at ICU admission rate, endotracheal intubation rate within 24 hours, length of ICU stays, length of hospital stays, and modified Rankin scale score at discharge. The adverse effects were observed in both groups. Levetiracetam showed less adverse effects than fosphenytoin (p value- 0.073 at 30 minutes, 0.011 at 24 hours, 0.430 at 7 days or hospital discharge whichever came first). Sedation, itching and rash were more common in fosphenytoin groups than levetiracetam groups. All cause in-hospital mortality is similar in both groups (6.5% vs 9.7%, p value < 0.987). Regarding the cost of the total length of the treatment, fosphenytoin and levetiracetam has similar cost (p value 0.136). **Conclusion:** The present study suggests that levetiracetam and fosphenytoin had similar efficacy in the treatment of adult convulsive status epilepticus patients. Adverse effect was less in levetiracetam than fosphenytoin group.

Keywords: Status epilepticus, Levetiracetam, Fosphenytoin

Date of submission: 11.04.2026

Date of acceptance: 29.04.2026

DOI: <https://doi.org/10.3329/bjm.v37i20.89293>

Citation: Islam MA, Ahmed KGU, Mahmud R. The Efficacy and Safety of Levetiracetam versus Fosphenytoin in Convulsive Status Epilepticus: An Open Label Clinical Trial in Dhaka Medical College Hospital. *Bangladesh J Medicine* 2026; Vol. 37, No. 2(1): pp. 210-211

Affiliations:

1. National Institute of Neurosciences & Hospital , Sher-E-Bangla Nagar, Dhaka, Bangladesh. E-mail: amirulislamk18@gmail.com
2. Dhaka Medical College, Dhaka, Bangladesh.