

A Double-Blind, Multicentre, Randomised, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Adjunctive Treatment with Oral Levetiracetam (LEV), in Adult and Paediatric Subjects (4 to 65 Years) Suffering From Idiopathic Generalised Epilepsy With Primary Generalised Tonic-Clonic (PGTC) Seizures

Short title: Levetiracetam for the Treatment of Generalised Epilepsy in Children and Adults

Background	<ul style="list-style-type: none">• The term 'epilepsy' is derived from the Greek word 'epilamvanein', which means 'to seize' or 'to attack'. It involves episodes of excessive electrical activity in the brain that can manifest in many different ways, with the episodes being called seizures.¹• Some seizures manifest as only an unusual feeling or sensation, while others may involve temporary loss of awareness of surroundings. Other seizure types result in the patient falling to the ground with jerky body movements, tongue biting, urination, or loss of bowel control.²• Partial seizures involve only a limited region of the brain, whereas generalized seizures involve the whole brain.¹
Purpose of the study	<ul style="list-style-type: none">• To determine if add-on treatment with oral levetiracetam (Keppra[®] tablets), in combination with 1 to 2 other medicines used to treat seizures, improves seizure control in children and adults, with idiopathic (i.e., of unknown cause) generalised epilepsy with primary generalised seizures, who had failed to improve with other treatments.• To determine if levetiracetam is well tolerated by these patients.
Study participants	<ul style="list-style-type: none">• The study included 164 male and female patients aged 4 to 65 years, with weight of at least 20 kg, with idiopathic generalised epilepsy and experiencing at least three generalised seizures during the 8-week baseline period despite treatment with 1 or 2 other antiepileptic medicines.• Patients were taking a maximum of 2 medicines, other than levetiracetam, to treat generalised seizures.• They kept taking those medicines during the conduct of the study.
Study design and research methodology	<ul style="list-style-type: none">• The study was conducted in 57 centers across Australia, Canada, Estonia, Mexico, New Zealand, Poland, Russia, United Kingdom and the United States between September 2001 and June 2005. Patients participated in the study for a maximum of 34 weeks.• The patients were given either levetiracetam or a placebo, orally, two times a day.• After 24 weeks of total medicine exposure, the patients were followed to document the number of generalised seizures they experienced per week during the study. The percentage of patients in whom the number of seizures decreased by half and the percentage of patients who had no seizures were calculated.• Side effects were also studied.
Key findings	<ul style="list-style-type: none">• More patients in the group receiving levetiracetam compared with those receiving placebo:<ul style="list-style-type: none">○ Showed decreased number of generalised seizures per week.○ Showed decreased number of seizures by at least half.○ Achieved seizure freedom.• Most of the side effects were mild to moderate in intensity.<ul style="list-style-type: none">○ The most common side effects reported in at least 5% of the patients in both the treatment groups were nasopharyngitis (viral infection of the upper respiratory system), headache, fatigue, dizziness, nausea, diarrhoea, somnolence (drowsiness), influenza (flu), irritability, mood swings, contusion (bruise), urinary tract infection and back pain.• Patients who completed the study and were willing to continue treatment with levetiracetam were included in a follow-up study conducted over 4 years to assess the long-term safety and efficacy of levetiracetam [NCT00150748].
Peer-reviewed publication	Berkovic SF, Knowlton RC, Leroy RF, et al. Placebo-controlled study of levetiracetam in idiopathic generalized epilepsy. <i>Neurology</i>. 2007;69(18):1751-1760.
Peer-reviewed publication of follow-up trial	Delanty N, Jones J, Tonner F. Adjunctive levetiracetam in children, adolescents, and adults with primary generalized seizures: open-label, noncomparative, multicenter, long-term follow-up study. <i>Epilepsia</i>. 2012;53(1):111-119.

References:

1. Singh M, Kaur S. Epilepsy detection using EEG: An overview. *Int J Inf Technol Knowl Manag*. 2012;6:3-5.
2. Kellinghaus C, Luders H. Classification of seizures. In: Wyllie E, eds. *Wyllie's Treatment of Epilepsy Principles and Practice*. 5th ed. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins; 2011:134-143.

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