

# Open-Label, Single-Arm, Multicentre, Pharmacokinetic, Safety and Tolerability Study of Levetiracetam Intravenous Infusion in Children (4-16 Years Old) With Epilepsy

**Short title: Levetiracetam for the Treatment of Epilepsy in Children (4 - 16 Years Old)**

<b>Background</b>	<ul style="list-style-type: none"><li>• 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.<sup>1</sup></li><li>• 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.<sup>2</sup></li><li>• Partial seizures involve only a limited region of the brain, whereas generalized seizures involve the whole brain.<sup>1</sup></li></ul>
<b>Purpose of the study</b>	<ul style="list-style-type: none"><li>• To determine if add-on treatment or monotherapy (i.e., treatment using a single therapy) with levetiracetam provided intravenously (Keppra<sup>®</sup> injection) had an acceptable safety and tolerability profile in children with any type of epilepsy (except one type of epilepsy called 'status epilepticus') who are unable to take oral medicine.</li><li>• To study the effect of levetiracetam, provided intravenously, in the body.</li></ul>
<b>Study participants</b>	<ul style="list-style-type: none"><li>• The study included 33 male and female children, aged 4 to 16 years, with weight above 10 kg, with any type of epilepsy (except one type of epilepsy called 'status epilepticus') requiring short-term in-hospital levetiracetam intravenous treatment.</li></ul>
<b>Study design and research methodology</b>	<ul style="list-style-type: none"><li>• The study was conducted in 18 centres across Belgium, France, Germany, Mexico, Turkey and the United States between September 2007 and February 2010. Patients participated in the study for a maximum of 25 days.</li><li>• The patients were given either low or high dose of levetiracetam, intravenously, twice a day.</li><li>• After 4 days of total levetiracetam exposure, the patients were followed for saliva and blood plasma concentrations of levetiracetam.</li><li>• Side effects were also studied.</li></ul>
<b>Key findings</b>	<ul style="list-style-type: none"><li>• The plasma and saliva concentrations of levetiracetam were found to be in the expected range.</li><li>• More than half of the patients reported treatment-related side effects during the study period.</li><li>• Most of the side effects were mild to moderate in intensity.</li><li>• The most common side effects reported in at least 9% of the patients were convulsion, vomiting, nausea, dry mouth, pyrexia (fever) and hypotension (low blood pressure).</li><li>• Convulsion, vomiting, nausea and hypotension were the most frequently reported side effects in patients receiving low dose of levetiracetam, and dry mouth and pyrexia (fever) in patients receiving high dose of levetiracetam.</li><li>• No follow-up trials are foreseen for this study.</li></ul>
<b>Peer-reviewed publication</b>	<p><a href="#">Weinstock A, Ruiz M, Gerard D, et al. Prospective open-Label, single-arm, multicenter, safety, tolerability, and pharmacokinetic studies of intravenous levetiracetam in children with epilepsy. <i>J Child Neurol.</i> 2013;28 (11);1423-1429.</a></p>

## 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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